

**Submitter :** Mr. Michael Koeplinger  
**Organization :** Spencer Twp. Fire/Rescue  
**Category :** Local Government

**Date:** 12/31/2007

**Issue Areas/Comments**

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

**Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007**

I am not only the fire Chief of Spencer Twp. Fire/Rescue I am also an EMT for an ambulance company. I have a unique perspective on this new ruling, I not only see what it means from the administration side but from the end user side as well. From the administrators position the Government is inodating us in useless and unneeded paperwork. I am in charge of a small rural fire department with very limited resources, outdated computers that work when they want to, limited storage space to store all the extra paperwork this will generate and limited personel to keep tract of all the paperwork. You need to stop paying people to sit behind a desk and think of what new form we can come up with today. Instead put a commity together with people from private and public sector. Example voluntary fire departments (like us), full time fire departments, ambulance companies, hospitals etc.. These represntatives should be from different parts of the country to have a better view of what is needed to do the job. Now from the perspective of the end user the EMT. It has been my experierance that if you can not get the patient to sign due to they are not willing to sign or are unable to sign you will not get any body else to sign. The reason nobody else will sign is they do not want to get involved or they think they will be responceible for the bill or that they could be sued. I have herd all of these reasons given for not signing. So in effect you have put all of the BURDEN on the EMT to try to explain why we need a signature, to beg hospital or nursing home staff to sign, gather a ton more paperwork just to prove the transport took place. The only thing you have not asked for is our first born. Throwing more paperwork at the problem is not going to fix it. We are more than willing to help you but you have to help us by not drowning us in paperwork and RED TAPE. If you would like to discuss this further you can reach me at (419)865-2101.

Thank you for your time in this matter.  
Michael Koeplinger  
Chief Spencer Fire/Rescue

**Submitter :** Ms. Anne Lewis  
**Organization :** SMDC Health System  
**Category :** Health Care Professional or Association  
**Issue Areas/Comments**

**Date:** 12/31/2007

**GENERAL**

**GENERAL**

Please see the attachment for comments about the antimarkup rule.

CMS-1385-FC-231-Attach-1.DOC

#  
231

December 31, 2007

SMDC Health System  
400 East 3rd Street  
Duluth, MN 55805

Via Electronic Transmission to <http://www.cms.hhs.gov/eRulemaking>.

Centers for Medicare & Medicaid Services  
DHHS

Attention: CMS-1385-FC  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850

Re: File Code CMS-1385-FC

SMDC Health System ("SMDC") would like to offer comments about the new anti-markup rule published at 72 F.R. 66222. The new rule, perhaps inadvertently, arbitrarily penalizes multi-specialty practices. SMDC also believes that the rule exceeds CMS' authority under the authorizing statute because the statute establishes supervision as the factor for determining who has provided a diagnostic test.

We wish to focus our comments on the requirement that services must be provided in a building where the clinic provides "substantially the full range of patient care services that the physician organization provides generally," 42 CFR 414.50(a)(2)(iii). This requirement has major financial and operational implications for multispecialty systems that perform lab, imaging or other diagnostic work. Depending on how the phrase "full range" is interpreted, it may force patients that receive care from organizations that provide comprehensive care over a broad geographic area to travel considerable distances to receive diagnostic services. Finally, the new rule also has a perverse negative impact on physician practices that permit physicians to perform physician interpretations either at clinic space devoted exclusively to interpretations, in space leased in a hospital or at the physician's home. Our detailed comments are below.

**1. The rule arbitrarily penalizes organizations that provide services in a centralized location. It also may make it very difficult for organizations that care for patients over a wide geographic area to provide diagnostic services.**

Like many integrated health care systems, SMDC performs some of our lab and imaging in a centralized building. Under the final rule, we are deemed to be "purchasing" the tests from our own employed technician. It is hard to understand what policy is advanced by the rule.

Imagine two clinics. Both pay an MRI technician \$75,000 a year, or about \$1500/week, or \$300/day. The technician does about 15 scans a day. The only difference between the two clinics is that one clinic provides the full range of its services in one building, the other has a building designated exclusively for diagnostic services. Under the new rule, the first clinic may

bill the full Medicare fee schedule for the technical component of the MRI, or about \$450. The second clinic may only bill Medicare what it pays the technician; \$20 for a scan. No policy or logic underlies this dramatic reimbursement distinction. In both cases, the clinic is responsible for the cost of all overhead, including purchasing the equipment, maintaining the space, scheduling and billing. In both cases the clinic is responsible for supervising the tests. The services are being provided by clinic employees. There is no reason to characterize the services provided at a centralized location as “purchased.” The notion that the clinic can “purchase” the test from its own employee is bizarre; it is saying that the clinic is purchasing the test from itself.

The new rule sets Medicare reimbursement far below the cost of providing the service. The reimbursement is capped at the cost of one of the inputs. The rule makes it impossible for a clinic to break even on diagnostic tests done in a centralized building. These are services provided by SMDC’s employees, under SMDC’s supervision. There is no reason to characterize these tests as “purchased.” Preventing a clinic from recovering its overhead costs actively penalizes clinics for providing care to Medicare patients.

In addition, SMDC provides services to patients over a broad geographic area. In many locations we provide some, but not all, of our services. More specialized services are focused in larger centers; in rural areas patients may receive a subset of care, traveling only when specialized care is required. The final rule does not define the phrase “substantially the full range of patient care services.” That lack of regulatory clarity may result in carriers or others concluding that many rural locations do not “provide substantially the full range of physician services.”

For example, a small town clinic operated by SMDC may have only a few physicians, all of whom are likely Family Practitioner . That clinic will not offer the full range of specialty physicians found at SMDC’s main clinic in Duluth. If someone concludes that SMDC is not providing a “full range of services” at the small town clinic, providing diagnostic tests to patients at that clinic would be a money losing proposition. As a result, SMDC may be unable to provide diagnostic services at its small regional clinic sites, which sometimes offer the only physician services in town. That result would harm patient care. It is possible, perhaps even likely, that CMS does not intend to interpret the phrase “substantially the full range of patient care services” to be interpreted in this fashion, but the final rule is quite ambiguous.

**2. The statute only applies to “diagnostic tests” covered under 1861(s)(3). Interpretations are “physician services” covered under 1861(s)(1). Therefore, the anti-markup statute does not apply to interpretations.**

“Diagnostic tests” are covered under 1861(s)(3), while physician services are covered under 1861(s)(1). The anti-markup statute refers only to “diagnostic tests” not to “physician services.” In recent rulemaking, CMS has gone to some lengths to emphasize that each number under 1861(s) represents a separate and distinct benefit. These efforts began in 2001 when CMS amended 42 CFR 410.26(a)(7) to read that “services and supplies” incident to a physician’s services were limited to services and supplies “not specifically listed in the Act as a separate

benefit included in the Medicare program.” In 2002, CMS elaborated on that theme as part of the 2003 physician fee schedule, stating:

“Therefore, only services that do not have their own benefit category are appropriately billed as incident to a physician service. Examples of benefit categories are diagnostic X-ray tests (section 1861(s)(3) of the Act) and influenza vaccine and its administration (section 1861(s)(10)(A) of the Act.)”

67 FR 79966, 79994. In the September 5<sup>th</sup> Stark III final rule, 72 FR 51012, 51016, CMS reiterated that only services that “do not have their own separate and independently listed benefit category” under 1861(s) may be billed incident to a physician’s services. Since the official CMS position is that 1861(s)(1) and 1861(s)(3) are separate benefits, CMS cannot interpret a statute referring specifically to 1861(s)(3) as also applying to 1861(s)(1).

CMS’ assertion in the preamble to the final rule that perhaps the statutory omission was inadvertent is disingenuous. If Congress had meant to include the phrase “physician services” in the statute, it was free to do so over the ensuing 20 years. The opening sentence of the anti-markup statute refers specifically to “diagnostic tests” and “1861(s)(3).” It makes no mention of “physician services” or “1861(s)(1)”. The statute refers to “diagnostic test” or “test” eleven times. It never makes any reference to the “interpretation.” CMS does not have the authority to disregard the statute and interpret the reference to 1861(s)(3) as a reference to 1861(s)(1), particularly given that CMS’ other interpretations have highlighted the fact that each benefit in 1861(s) is unique. CMS must be consistent when interpreting the statute. If the agency concludes that Congress intended each of the categories under 1861(s) to be separate and distinct for purposes of the “incident to” benefit, then they must also be separate and distinct for purposes of the anti-markup statute.

### **3. A clinic should not be deemed to be “purchasing” an interpretation from its own employee simply because the employee is not in the main clinic space.**

We certainly understand CMS’s concern about purchased interpretations. But we do not understand why those concerns would extend to services performed by SMDC employees. Electronic communication makes it relatively easy for physicians to provide interpretive services offsite, whether at home, at space leased from a hospital or in another location. There is no reason that the clinic should receive lower reimbursement based entirely on the location of physician when s/he performs the exam. The clinic is incurring all of the overhead costs associated with the scan. (The site of service differential for services provided in the hospital is clearly distinguishable. When services are provided in hospital space the hospital is incurring much of the overhead. For services provided at a physician’s home, the clinic is responsible for the full overhead cost.)

Limiting the clinic’s reimbursement to the amount billed by the physician prevents the clinic from recovering any of its overhead costs, including, ironically, the costs associated with acquiring the equipment that permits the physician to read at an off-site location as well as the cost of preparing the bills, scheduling the appointment, preparing the report and operating the clinic. In most clinics, overhead costs constitute approximately half of the total clinic revenue.

The new rule prevents clinics from recovering those costs when interpretations are done at the physician's home, or at space devoted exclusively to providing interpretations. Patient care improves when physicians are able to provide interpretations quickly. Requiring a physician to go to the clinic to perform a read when the same read could be done immediately on a computer at the physician's home unnecessarily places patients at risk.

**4. Under Section 1842(n) of the Social Security Act, commonly called the anti-markup provision, if a physician supervises a test, the anti-mark-up rule does not apply. To the extent the rule imposes additional requirements, it exceeds the authority granted by the statute.**

As you know, Section 1842(n) of the Social Security Act provides that:

If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment **does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test**, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

The bold language clearly limits applicability of the rule to situations where the test is neither performed nor supervised by the physician or a physician with whom the physician shares a practice.

As long as the physician provides the supervision required by Medicare rules, the anti-markup statute does not apply. CMS has used its regulatory authority to create the three levels of supervision for diagnostic tests found at 42 C.F.R. 410.32. The definition of general supervision states that "the physician's presence is not required during the performance of the procedure." If a physician (or someone with whom the physician shares a practice) is providing general supervision to a lab test, imaging, or other diagnostic test done offsite, the test is "supervised" as defined in the anti-markup statute and the physician is NOT purchasing the test. To the extent the new rule establishes additional requirements, it exceeds the authority of the statute. In particular, the requirement that the test must be provided "in the office of the billing physician," defined as space in which the physician organization provides "substantially the full range of

patient care services that the physician organization provides generally” is inconsistent with the statute.

The statute establishes supervision as the test for determining whether a diagnostic test is furnished by the physician or purchased. CMS does not have the authority to impose the anti-markup prohibition when a physician complies with CMS’ published rules regarding supervision of the diagnostic tests.

Sincerely,

Anne Lewis, Esq.  
Associate General Counsel

Teresa M. O’Toole, Esq.  
Associate General Counsel

**Submitter :** Ms. Anne Llewellyn  
**Organization :** Case Management Society of America  
**Category :** Health Care Professional or Association

**Date:** 12/31/2007

**Issue Areas/Comments**

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

December 31, 2007

Centers for Medicare & Medicaid Services  
Baltimore, Maryland

Re: Docket: CMS-1385-FC - Revisions to Payment Policies Under the Physician Fee Schedule: Medicare Interim Final Rule Physician Fee Schedule 2008 related to codes 99441, 99442, 99443, 98966, 98967, 98968

Dear Sir:

I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) interim final rule regarding revisions to payment policies under the proposed 2008 Medicare Physician Fee Schedule Docket CMS-1385-FC.

Case/care management is a collaborative process of assessment, planning, facilitation and advocacy for options and services to meet an individual's healthcare needs through communication and available resources (CMSA, 2002). As an essential part of the healthcare team, case managers routinely work directly with patients in support of medical management assessments, objectives, services, and health care coordination. The processes of health adherence assessment, education, and adherence monitoring are well within the scope of case/care management practice.

Professional case/care managers perform these responsibilities as a core function of their jobs. As licensed professionals, nurses, social workers case/care managers use proven techniques (e.g., health literacy assessment, readiness to change tool) in working with patients, caregivers, and fellow healthcare professionals toward measurable improvement in health status.

Case/care managers work collaboratively with physicians and pharmacists in coordinating and providing assessments and management services through individualized care planning and care coordination in collaboration with beneficiaries, care givers and families. In support of those interventions and services, we ask for reconsideration of the interim payment rule on CPT codes: 99441, 99442, 99443, 98966, 98967 & 98968 from an N status to payable codes by Medicare. These codes represent assessment and management services to beneficiaries such as:

- " Transition of care
- " Medication reconciliation
- " Health literacy assessment, medication knowledge, readiness to change
- " Motivational interviewing
- " Patient education
- " Medical Home coordination

Failure to provide appropriate incentives and funding for these codes affects the alignment of care coordination quality between providers, especially at the various levels for transitions of care within settings, between settings, and between health states. Poor transitions of care may result in poor outcomes such as incorrect treatments, medication errors, delay in diagnosis and treatment, readmissions, patient complaints, increased health care costs).

I believe that by requesting funding support for these six codes, providers will more readily integrate case/care managers in support of the care management concepts such as the Medicare Medical Home Demonstration (MMHD), pay for performance programs, and various collaborative care models which CMS and other regulatory agencies are discussing.

I urge CMS to adopt a payable ruling structure for these much needed codes to ensure consistency, accountability, and improved quality of care for beneficiaries. I thank you for your consideration of these comments on this Interim Final Rule.

Sincerely,

Anne Llewellyn, RN-BC, MS, BHSA, CCM, CRRN  
Sent via email

**Submitter :** Ms. Kimberly Otte  
**Organization :** Mayo Foundation  
**Category :** Health Care Professional or Association

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see the attachment for comments about the anti-markup rule.

CMS-1385-FC-233-Attach-1.DOC

Kimberly K. Otte, Esq.  
Mayo Foundation  
200 First Street SW  
Rochester MN 55905

December 31, 2007

Via Electronic Transmission to <http://www.cms.hhs.gov/eRulemaking>.

Centers for Medicare & Medicaid Services  
DHHS

Attention: CMS-1385-FC  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850

Dear CMS:

Re: File Code CMS-1385-FC

On behalf of Mayo Foundation, I would like to offer comments about the new anti-markup rule published at 72 F.R. 66222. We believe that the new rule exceeds CMS' authority under the authorizing statute and arbitrarily penalizes multispecialty practices. We wish to focus our comments on the requirement that services must be provided in a building where the clinic provides "substantially the full range of patient care services that the physician organization provides generally," 42 CFR 414.50(a)(2)(iii). This requirement has major financial and operational implications for multispecialty systems that perform lab, imaging or other diagnostic work in a centralized building. In particular, the new rule means that if Mayo Clinic performs all of its lab in a centralized facility, Mayo Clinic is deemed to be purchasing the tests from itself and its reimbursement is capped at the salary Mayo Clinic pays its technicians. Mayo will not be able to recover any of its costs for equipment, the facility or other operations that are essential to providing medical care. The new rule also has a perverse negative impact on physician practices that permit physicians to perform physician interpretations either at clinic space devoted exclusively to interpretations, in space leased in a hospital or at the physician's home. Our detailed comments are below.

**1. Under Section 1842(n) of the Social Security Act, commonly called the anti-markup provision, if a physician supervises a test, the anti-mark-up rule does not apply. To the extent the rule imposes additional requirements, it exceeds the authority granted by the statute.**

As you know, Section 1842(n) of the Social Security Act provides that:

If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment **does not indicate that the billing**

**physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:**

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

The bold language clearly limits applicability of the rule to situations where the test is neither performed nor supervised by the physician or a physician with whom the physician shares a practice.

As long as the physician provides the supervision required by Medicare rules, the anti-markup statute does not apply. Through your regulatory authority, at 42 C.F.R. 410.32 you created three levels of supervision for diagnostic tests. The definition of general supervision states that “the physician's presence is not required during the performance of the procedure.” If a physician (or someone with whom the physician shares a practice) is providing general supervision to a lab test, imaging, or other diagnostic test done offsite, the test is “supervised” as defined in the anti-markup statute and the physician is NOT purchasing the test. To the extent the new rule establishes additional requirements, it directly contradicts the statute. In particular, the requirement that the test must be provided “in the office of the billing physician,” defined as space in which the physician organization provides “substantially the full range of patient care services that the physician organization provide generally” is inconsistent with the statute.

The statute establishes supervision as the test for determining whether a diagnostic test is furnished by the physician or purchased. CMS does not have the authority to impose the anti-markup prohibition when a physician complies with CMS’ published rules regarding supervision of the diagnostic tests.

## **2. Even if the rule did not exceed the statutory authority, the rule arbitrarily penalizes organizations that provide services in a centralized location.**

Like many large multi-specialty clinics, we perform some of our lab and imaging in a centralized building. Under the final rule, we are deemed to be purchasing the tests from our own employed technician. It is hard to understand what policy is advanced by the rule.

Imagine two clinics. Both pay an MRI tech \$75,000 a year, or about \$1500/week, or \$300/day. The tech does about 15 scans a day. The only difference between the two clinics is that one clinic provides the full range of its services in one building, the other has a building

designated exclusively for diagnostic services. Under the new rule, the first clinic may bill the full Medicare fee schedule for the technical component of the MRI, or between \$400 and \$500 dollars. The second clinic may only bill Medicare what it pays the technician; \$20 for a scan. No policy or logic underlies this dramatic reimbursement distinction. In both cases, the clinic is responsible for the cost of all overhead, including purchasing the equipment, maintaining the space, scheduling and billing. In both cases the clinic is responsible for supervising the tests. The services are being provided by clinic employees. There is no reason to characterize the services provided at a centralized location as “purchased.” The notion that the clinic can purchase the test from its own employee is entirely counterintuitive.

The problem with lab is identical. In fact, a clinic with multiple locations may seek to control costs by using one centralized lab. Under your rule, unless the lab is in space where the physicians perform the full range of services, the clinic may only recoup the cost of tech’s salary, with no other overhead for space, equipment or anything else. This lab issue is a significant concern to Mayo Foundation, as centralized lab is a fundamental part of Mayo’s medical model.

For both lab and imaging, the new rule sets Medicare reimbursement far below the cost of providing the service. The reimbursement is capped at the cost of one of the inputs. The rule makes it impossible for a clinic to break even on diagnostic tests done in a centralized building. These are services provided by a clinic’s employees, under the clinic’s supervision. There is no reason to characterize these tests as “purchased.” Preventing a clinic from recovering its overhead costs actively penalizes clinics for providing care to Medicare patients.

**3. The statute only applies to “diagnostic tests” covered under 1861(s)(3). Interpretations are “physician services” covered under 1861(s)(1). Therefore, the anti-markup statute does not apply to interpretations.**

“Diagnostic tests” are covered under 1861(s)(3), while physician services are covered under 1861(s)(1). The anti-markup statute refers only to “diagnostic tests” not to “physician services.” In recent rulemaking, CMS has gone to some lengths to emphasize that each number under 1861(s) represents a separate and distinct benefit. These efforts began in 2001 when you amended 42 CFR 410.26(a)(7) to read that “services and supplies” incident to a physician’s services were limited to services and supplies “not specifically listed in the Act as a separate benefit included in the Medicare program.” In 2002, you elaborated on that theme as part of the 2003 physician fee schedule, stating that:

“Therefore, only services that do not have their own benefit category are appropriately billed as incident to a physician service. Examples of benefit categories are diagnostic X-ray tests (section 1861(s)(3) of the Act) and influenza vaccine and its administration (section 1861(s)(10)(A) of the Act.)”

67 FR 79966, 79994. In your September 5<sup>th</sup> Stark III final rule, 72 FR 51012, 51016, you reiterated that only services that “do not have their own separate and independently listed benefit category” under 1861(s) may be billed incident to a physician’s services. Since your official position is that 1861(s)(1) and 1861(s)(3) are separate benefits, you cannot interpret a statute referring specifically to 1861(s)(3) as also applying to 1861(s)(1).

CMS' assertion in the preamble to the final rule that perhaps the statutory omission was inadvertent is disingenuous. If Congress had meant to include the phrase "physician services" in the statute, it was free to do so over the ensuing 20 years. The opening sentence of the anti-markup statute refers specifically to "diagnostic tests" and "1861(s)(3)." It makes no mention of "physician services" or "1861(s)(1)". The statute refers to "diagnostic test" or "test" eleven times. It never makes any reference to the "interpretation." CMS does not have the authority to disregard the statute and interpret the reference to 1861(s)(3) as a reference to 1861(s)(1), particularly given that CMS' other interpretations have highlighted the fact that each benefit in 1861(s) is unique. CMS must be consistent when interpreting the statute. If the agency concludes that Congress intended each of the categories under 1861(s) to be separate and distinct for purposes of the "incident to" benefit, then they must also be separate and distinct for purposes of the anti-markup statute.

**4. A clinic should not be deemed to be "purchasing" an interpretation from its own employee simply because the employee is not in the main clinic space.**

We certainly understand your concern about purchased interpretations. But we do not understand why those concerns would extend to services performed by our employees. Electronic communication makes it relatively easy for physicians to provide interpretive services offsite, whether at home, at space leased from a hospital or in another location. There is no reason that the clinic should receive lower reimbursement based entirely on the location of the physician when s/he performs the exam. The clinic is incurring all of the overhead costs associated with the scan. (The site of service differential for services provided in the hospital is clearly distinguishable. When services are provided in hospital space the hospital is incurring much of the overhead. For services provided at a physician's home, the clinic is responsible for the full overhead cost.)

Limiting the clinic's reimbursement to the amount billed by the physician prevents the clinic from recovering any of its overhead costs, including the costs associated with acquiring the equipment that permits the physician to read at home, the cost of preparing the bills, scheduling the appointment, preparing the report and operating the clinic. In most clinics, overhead costs constitute approximately half of the total clinic revenue. Your rule would prevent clinics from recovering those costs when interpretations are done at the physician's home, or at space devoted exclusively to providing interpretations. This rule will force clinics to choose between losing money on these interpretations or forbidding interpretations offsite.

I hope that you will consider these comments and revise the rule so that it does not apply to services provided by clinic personnel.

Sincerely,

Kimberly K. Otte, Esq.  
Legal Counsel

**Submitter :** Mr. Gerald Telzrow  
**Organization :** Lyndhurst Fire Department  
**Category :** Local Government

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Requiring the signature of patients transported by the public EMS service is difficult under most circumstances. We are dealing with emergency situations and to ask the patient at the same time to sign a form allowing us to collect reimbursement for EMS services and transport give the public a perception that we are more interested in collecting money than we are in assiting them in their time of need. This is very bad PR for the fire service!

**Submitter :** Dr. Thomas Russell  
**Organization :** American College of Surgeons  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1385-FC-235-Attach-1.PDF



# American College of Surgeons

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e-mail: postmaster@facs.org ACS Web site: www.facs.org

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December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Weems:

On behalf of the 74,000 Fellows of the American College of Surgeons, we are pleased to submit comments on the Final Rule posted on November 1, 2007, which addressed changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies.

### Interim Relative Value Units (RVUs)

For calendar year (CY) 2008, the Centers for Medicare & Medicaid Services (CMS) received work RVU recommendations for 169 new and revised CPT codes from the AMA/Specialty Society RVS Update Committee (RUC) and 7 recommendations from the Health Care Professional Advisory Committee (HCPAC). We appreciate that CMS continues to accept the peer-reviewed recommendations that come from this expert panel of physicians and allied health care providers who dedicate a good deal of volunteer time to this process. However, we would like to comment on CMS's rejection of the RUC recommendations for the open reduction and internal fixation (ORIF) codes. In the final rule, CMS indicates that these codes were originally part of the 5-Year Review of work RVUs and were referred to the CPT Editorial Panel by the RUC for further clarification. After revisions were approved by the CPT Editorial Panel, the American Academy of Orthopaedic Surgeons, along with other specialties, surveyed all of the codes, using the 5-year review survey instrument. The specialty recommendations were required to



meet 5-year review compelling evidence standards in order to make a recommendation for a change in the work RVU. We do not understand CMS's application of budget neutrality to this group of codes. These codes were clearly part of a 5-year review process, and the results of that process require any budget neutrality to be applied across all codes. CMS's treatment of this group of codes is inconsistent with the 5-year review process as we understand it. We urge CMS to review its decision and accept the work RVUs that the RUC recommended. Further, because the RUC continues to review codes at CMS's request on a "rolling 5-year basis," we urge CMS to apply budget neutrality across all codes, with respect to all 5-year review work RVU recommendations that CMS accepts, regardless of when they are presented.

### **Budget Neutrality Adjustment**

In the final rule, CMS rejects what we believe to be the almost unanimous recommendation to apply budget neutrality to the fee schedule conversion factor instead of creating a separate work adjuster. We continue to believe very strongly that it is confusing and even misleading to publish work values in Addendum B of the proposed rule and elsewhere that are not "real" or "true" for Medicare because they are adjusted downward by a budget neutrality factor prior to payment being made. Further, because the proportion of total RVUs included in the work value for individual services varies widely across the fee schedule – indeed, many services have no physician work values assigned to them – the work adjuster spreads the "cost" of the 5-year review unevenly across services and specialties and distorts the relativity of the fee schedule. This makes no sense in a process that is intended to improve the relativity of work RVUs. We reiterate our request that budget neutrality adjustments made as a result of changes in services included in the 5-year review should be applied to the conversion factor rather than through a separate work adjuster.

For example, CMS has chosen to offset the agreed upon 32 percent increase in the work of anesthesia services by additional adjustments to the PFS budget neutrality adjuster for work. CMS estimates that the increase in the anesthesia conversion factor would result in an additional 1.0 percent increase in the budget neutrality adjuster for work. To offset the net increases in work values proposed by CMS, including those for anesthesia services, CMS is proposing a revised work adjuster of approximately 0.8816, which would correspond to a decrease of 11.84 percent for all work RVUs. If budget neutrality adjustments are applied to the conversion factor rather than work RVUs, then the effect of budget neutrality would be explicit and the effects more evenly distributed.

### **Equipment Cost per Minute**

The calculation of equipment cost per minute has many variables. Some of these variables were addressed in the CY 2008 PFS proposed rule, soliciting comments. In this CY 2008 PFS final rule, CMS provides response to comments about a few variables, but we remain concerned that CMS has not developed a process that can address all the variables in an ongoing fashion, so that up to date and credible information is used in the equation for equipment cost per minute:  $(1/(\text{minutes per year} * \text{usage})) * \text{price} * ((\text{interest rate}/(1-(1/((1 + \text{interest rate}) * \text{life of equipment})))) + \text{maintenance})$ .

Equipment Usage Percentage. In the CY 2008 PFS proposed rule, CMS acknowledged that the 50 percent across the board usage rate for all equipment does not capture the actual usage rates for all equipment, but that CMS did not have sufficient empirical evidence to justify an



alternative. Comments on alternative percentages and different approaches were solicited and received. In the CY 2008 final rule, CMS has elected to maintain the current assumptions, but notes that these matters should continue to be examined for accuracy. There are 574 priced "equipment" items in the CMS records. Of these 574 items, only 52 are over \$100,000. The most expensive of these 52 listings are actually "rooms" or imaging equipment for rooms, ranging from \$1-\$4.4 million. CMS indicates it does not have sufficient evidence to justify an alternative utilization rate, however, does not explain what efforts have been put into reviewing this issue. We urge CMS to develop a process that can begin to address utilization rates.

Interest Rate. In the CY 2008 PFS proposed rule, CMS discussed the basis for the current interest rate of 11 percent. In the CY 2008 PFS final rule, CMS indicates that 11 percent continues to be an appropriate assumption. This assumption was based on an analyses of data provide by the Small Business Administration regarding prevailing loan rates for small businesses. The criteria used was loans for equipment with a cost over \$25,000 and a useful life of over seven years. Of the 574 priced equipment items in the CMS files, less than half have a useful life of over seven years. If CMS can gain information about loan rates for criteria such as equipment cost and useful life, then it should be possible to have interest rates assigned on a item basis just as the useful life is assigned on an item basis. The interest rate on a \$600 loan for an anoscope with a useful life of 3 years is not likely to be the same as a \$4.4 million loan for a Lincac SRS system with a useful life of 7 years. We urge CMS to develop a process that can begin to address interest rates in a less global fashion.

Again, the College appreciates the opportunity to submit comments on the Final Rule. If you have any questions regarding our comments or wish to discuss then further, please contact Cynthia Brown, Director of the Division of Advocacy and Health Policy, at (202) 337-2701.

Sincerely,

A handwritten signature in cursive script that reads "Thomas R. Russell".

Thomas R. Russell, MD, FACS  
Executive Director

TRR:cb:wo

**Submitter :** Ms. Beverly Crum

**Date:** 12/31/2007

**Organization :** Ketchikan General Hospital

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I find this distressing that limited ER staff including physicians will have to put the ambulance patient care on hold to sign a report. Who is to do emergency procedures in an ER with one RN on duty? Do I call for help, wake up the MD or sign the EMS report? What is my signature stating? I have heard a verbal report or read the written report or that I am accepting the patient? The written reports are not always available when the patient first arrives...especially when there is more than one presenting patient. This may delay patient care, isn't CMS causing their own EMTALA violation?

**Submitter :** Dr. PHILIP ALIOTTA  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-237-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

2732 TRANSIT ROAD  
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Telephone: 716-608-8700  
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## FOUNDING INDIVIDUAL MEMBERS

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K. Kent Chevli, M.D.

Richard N. Gilbert, M.D.

Joseph M. Greco, M.D.

Joseph A. Greco, M.D.

Christopher Kapp, M.D.

Chris M. Perotto, M.D.

Joseph D. Perrepatto, D.D.

John V. Plaski, M.D.

Frank R. Reinhardt, M.D.

Frank A. Scrima, M.D.

Joseph J. Marino, M.D.

Robert J. Susnowski, M.D.

Thomas J. Tuzicki, M.D.

John G. Wagle, M.D.

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

Dear Administrator Weems:

I am a urologist who practices in a large practice in Western New York. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

The final rule imposes an anti-markup provision on the technical and professional components of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the technical or professional component is purchased from an "outside supplier" or if it is performed at a site other than the office of the billing physician or other supplier. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on where the test is furnished. Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," i.e., the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

When the anti-markup rule applies to a diagnostic test, the amount of payment is affected by requiring that a "net charge" be calculated. CMS has given little guidance with respect to calculating the "net charge" when a service is provided by the employed technologists and physicians of a practice where those individuals are not compensated based on a per test basis. In addition, the CMS rules require that the "net charge" be calculated without regard to any overhead, including the cost of equipment or leased space.

Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, after relying upon CMS guidance with respect to the physician self-referral laws and regulations—will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients if the billing medical practice does not have a full service office where the test is provided. These changes will have a serious impact on geographically disbursed practices that have centralized services in a facility that is not their main location.

The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,



Philip Aliotta, M.D.

**Submitter :** Dr. KEVIN BARLOG  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-238-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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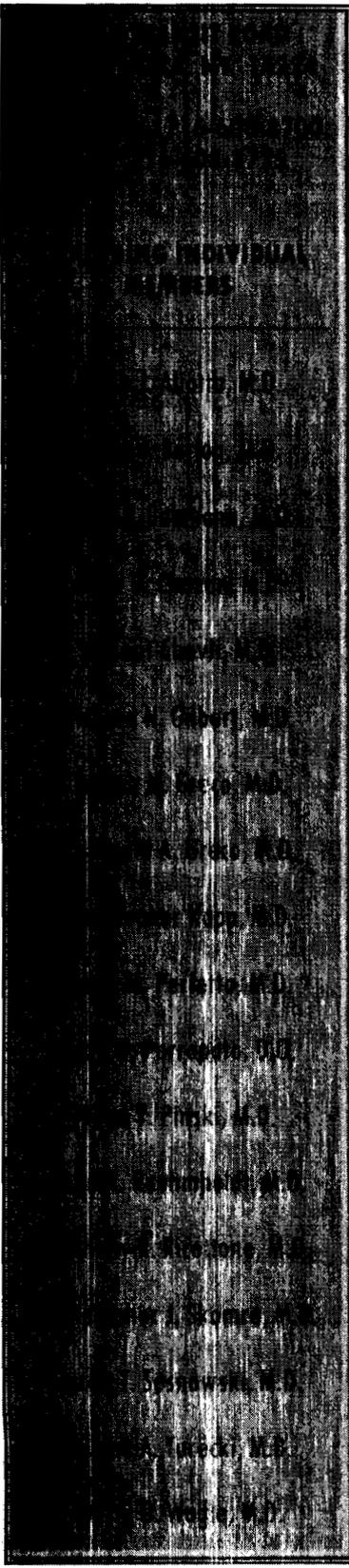
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Thank you for your consideration,



Christopher J. Skomra, M.D.



**Submitter :** Mr. Ken Jones  
**Organization :** Quest Medical, Inc.  
**Category :** Device Industry

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see the attached comment provided by Quest Medical, Inc. regarding recommendation for physician reimbursement for CPT 68816

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

Ref: Physician Payment Level for new CPT? 68816

CMS-1385-FC-239-Attach-1.PDF



**December 31, 2007**

Centers for Medicare & Medicaid Services  
 Department of Health and Human Services  
 Attn: CMS-1385-FC  
 Mail Stop C4-26-05  
 7500 Security Boulevard  
 Baltimore, MD 21244-1850

*Ref: Physician Payment Level for new CPT® 68816*

Dear Administrator:

This correspondence is in reference to the physician payment for new CPT® code 68816. In the final rule, the 2008 payment for this code is \$530 (non-facility) and \$181 (facility).

#### **Quest Medical**

Quest Medical, Inc. develops, manufactures, and distributes medical devices for a variety of medical and surgical markets. The markets our products provide solutions for include cardiac surgery, ophthalmic surgery, oncology, IV fluid and anesthesia delivery, and hemodialysis. Quest Medical makes several products for treatment of eye disorders, including several manual ophthalmic surgical devices used for less invasive treatments of occluded lacrimal ducts. LacriCATH® is our newest product line. The LacriCATH® balloon catheters are available in various sizes and configurations to accommodate both pediatric and adult patients. Pediatric ophthalmologists are the primary customers for this technology.

#### **Balloon Catheter Dilation of the Nasolacrimal Duct**

As background, the 68816 procedure is described as *Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation*. In this procedure, the typical patient is placed under anesthesia. The puncta are dilated. The lacrimal system is probed in the customary fashion, and the presence of the probe in the nose is confirmed. The probe is removed, and a balloon catheter is passed through the superior punctum, canalicular system and into the nasolacrimal duct down to the nasal floor. The presence of the balloon catheter in the nose is then confirmed. An inflation device is filled with sterile water or saline, connected to the balloon catheter, and the balloon is inflated for 90 seconds. The balloon is then deflated by releasing the lock mechanism on the inflation device. The inflation procedure is repeated a second time for 60 seconds, and again the balloon is deflated. The balloon is pulled proximally and positioned within the lacrimal sac and nasolacrimal duct. The balloon is inflated and deflated again using the same method described above. The balloon is deflated fully by aspirating residual fluid out of the balloon. The catheter is then rotated clockwise to minimize the profile of the deflated balloon and is gently withdrawn from the lacrimal system. Proper drainage is confirmed using an irrigating fluid with fluorescein dye.

This procedure has gained prominence. In the largest series reported, patients received balloon treatment after failed probing. Patients experienced duct clearance in a single treatment. In all cases, those patients receiving a stent instead of a balloon required a second physician encounter to remove the stent after the end of the global period. In addition, balloon treatment

**QUEST** Medical, Inc.

An **Atrion** company



was complication free (compared to 20% for stents).

### **2008 Physician Payment**

We appreciate CMS' efforts to ensure that the cost of the LacriCATH<sup>®</sup> technology is included in the non-facility payment rate for 68816. While only occasionally performed in the office setting, establishing a payment rate makes this a viable option for those rare patients considered candidates for office procedures. In general, the total payment seems quite low in this setting. Above the cost of the balloon (\$309), the total payment is a mere \$221.

We understand that a survey of approximately 30 ophthalmologists was performed to determine the time required to perform this procedure. While most pediatric ophthalmologists perform fewer than 15 of these procedures per year, in an era of declining reimbursement, any decrease is viewed with alarm, particularly among this specialty. An increase in the proposed physician work RVUs from 3.00 to 3.24 would maintain physician payment at the level for placing a stent tube (68815) and could reasonably be within the noise of the physician survey. We would not support a reduction in 68815

We believe in the LacriCATH<sup>®</sup> technology and are confident that – with a fair payment – pediatric ophthalmologists will continue to offer this procedure for their patients. We understand and deeply appreciate that the AMA and CMS have gone to great lengths to determine what a “fair” payment is. Many individuals involved in the process (physicians completing surveys, AMA Editorial Panel members, and the RUC) work on a volunteer basis to make affordable healthcare available. We are grateful for this. Consequently, we will double our efforts to make this technology as effective, easy to use, inexpensive and as cost-effective as we can.

Thank for this opportunity to comment on payment for 68816. If you have any questions, please contact me at 800-627-0226 ext 216.

Sincerely,

Ken Jones  
President  
Quest Medical, Inc.

**Submitter :** Dr. LOUIS BAUMANN  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-240-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

Dear Administrator Weems:

I am a urologist who practices in a large practice in Western New York. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

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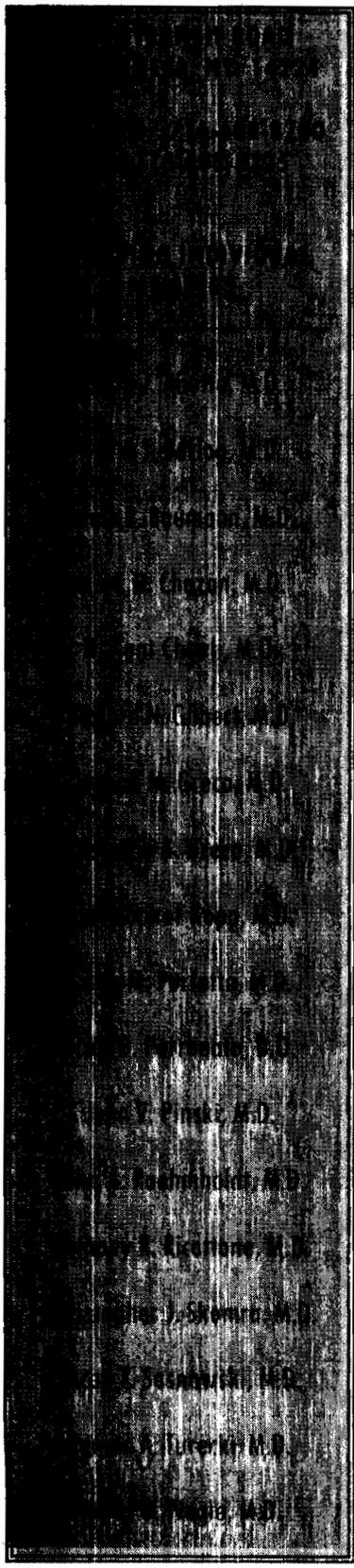
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Thank you for your consideration,



Louis R Baumann, M.D.



**Submitter :** Dr. KENT CHEVLI  
**Organization :** UROLOGIC IPA OF NEW YORK  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-241-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

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Richard N. Gilbert, M.D.  
Joseph M. Greco, M.D.  
Pasquale A. Grace, M.D.  
Christopher Kopp, M.D.  
Cathy M. Portante, M.D.  
Paul D. Parropan, D.O.  
John V. Pinski, M.D.  
John A. Rothenbaldt, M.D.  
Michael A. Scutella, M.D.  
Christopher J. Slamon, M.D.  
Robert Sosnowski, M.D.  
James A. Tuckey, M.D.  
James W. Wacht, M.D.

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
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Thank you for your consideration,



Kent Chevli, M.D.

**Submitter :** Dr. RICHARD GILBERT  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-242-Attach-1.PDF

#242

# UROLOGIC IPA OF NEW YORK, LLC

**2732 TRANSIT ROAD  
WEST SENECA, NY 14224**

**Telephone: 716-608-8700  
Fax: 716-608-8725**

**FOUNDING INDIVIDUAL  
MEMBERS**

Philip J. Aliotta, M.D.  
Kevin J. Barlog, M.D.  
Louis B. Baumann, M.D.  
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K. Kent Chevli, M.D.  
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Vincenzo A. Greco, M.D.  
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John D. Perrotato, D.O.  
John Y. Pinski, M.D.  
John J. Roemholdt, M.D.  
Thomas R. Ruffano, M.D.  
Christopher J. Skowro, M.D.  
Joseph T. Sosnowski, M.D.  
Thomas A. Toracki, M.D.  
Mark S. Wagle, M.D.

December 31, 2007

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Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
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Richard N. Gilbert, M.D.

**Submitter :** Dr. JOSEPH GRECO

**Date:** 12/31/2007

**Organization :** UROLOGIC IPA OF NEW YORK, LLC

**Category :** Physician

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-243-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

2732 TRANSIT ROAD  
WEST SENECA, NY 14224  
Telephone: 716-608-8700  
Fax: 716-608-8725

## FOUNDING INDIVIDUAL MEMBERS

- Philip J. Altieri, M.D.
- Kevin J. Barlog, M.D.
- Louis R. Baumann, M.D.
- Mark D. Chozun, M.D.
- R. Kent Chevli, M.D.
- Richard N. Gilbert, M.D.
- Joseph M. Greco, M.D.
- Salvatore A. Greco, M.D.
- Christopher Kopp, M.D.
- Enzo M. Portetto, M.D.
- David B. Perupeto, D.D.
- John Y. Polski, M.D.
- John A. Reinholdt, M.D.
- Anthony E. Riccio, M.D.
- Christopher J. Skampa, M.D.
- Richard J. Sosnowski, M.D.
- Thomas J. Tolvet, M.D.
- Joseph J. Tully, M.D.

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

Dear Administrator Weems:

I am a urologist who practices in a large practice in Western New York. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

The final rule imposes an anti-markup provision on the technical and professional components of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the technical or professional component is purchased from an "outside supplier" or if it is performed at a site other than the office of the billing physician or other supplier. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on where the test is furnished. Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," i.e., the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

When the anti-markup rule applies to a diagnostic test, the amount of payment is affected by requiring that a "net charge" be calculated. CMS has given little guidance with respect to calculating the "net charge" when a service is provided by the employed technologists and physicians of a practice where those individuals are not compensated based on a per test basis. In addition, the CMS rules require that the "net charge" be calculated without regard to any overhead, including the cost of equipment or leased space.

Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, after relying upon CMS guidance with respect to the physician self-referral laws and regulations—will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients if the billing medical practice does not have a full service office where the test is provided. These changes will have a serious impact on geographically disbursed practices that have centralized services in a facility that is not their main location.

The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,



Joseph M. Greco, M.D.

**Submitter :** Dr. PASQUALE GRECO  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-244-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

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Jacek T. Sosnowski, M.D.

James A. Turecki, M.D.

Datta G. Wagle, M.D.

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

Dear Administrator Weems:

I am a urologist who practices in a large practice in Western New York. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

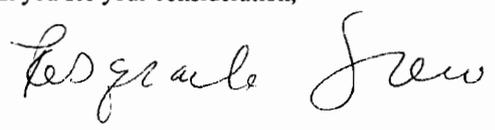
The final rule imposes an anti-markup provision on the technical and professional components of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the technical or professional component is purchased from an "outside supplier" or if it is performed at a site other than the office of the billing physician or other supplier. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on where the test is furnished. Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," i.e., the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

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Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, after relying upon CMS guidance with respect to the physician self-referral laws and regulations—will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients if the billing medical practice does not have a full service office where the test is provided. These changes will have a serious impact on geographically disbursed practices that have centralized services in a facility that is not their main location.

The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,



Pasquale A. Greco, M.D.

**Submitter :** Mr. Gil Irely

**Date:** 12/31/2007

**Organization :** Cedar Valley Medical Specialists, P.C.

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Please see our comments in the attachment. The comments relate to the anti-markup rule. Thanks you for your time.

CMS-1385-FC-245-Attach-1.DOC

Gil Irey  
Chief Executive Officer  
Cedar Valley Medical Specialists, P.C.  
4150 Kimball Avenue  
Waterloo, IA 50701

Via Electronic Transmission to <http://www.cms.hhs.gov/eRulemaking>.

Dear CMS:

Re: File Code CMS-1385-FC

On behalf of the Cedar Valley Medical Specialists, P.C., I would like to offer comments about the new anti-markup rule. I believe that the new rule exceeds CMS' authority under the authorizing statute, and is bad policy. I wish to focus my comments on the requirement that services must be provided in a building where the clinic provides the full range of its services and the implications it has for clinics that might perform imaging or other diagnostic work in a building where there is a limited physician presence. Since many diagnostic tests are performed under general supervision, which does not require a physician presence, some tests are performed in buildings where there is no physician presence. Obviously, when the test merits a physician's presence, we have a physician there, but that does not mean that the full range of physician services are provided; the supervising physician is there to supervise the test, not offer every possible service. The new rule inexplicably treats tests performed under general supervision like tests purchased from an outside entity. The new rule also has a perverse negative impact on physician practices that permit physicians to perform reads either at clinic space devoted exclusively to interpretations, space leased in a hospital or at the physician's home. I would ask you to carefully consider changing the rule for the following reasons:

**1. Under Section 1842(n) of the Social Security Act, commonly called the anti-markup provision, if a physician supervises a test, the anti-mark-up rule does not apply. To the extent the rule imposes additional requirements, it is inconsistent with the statutory language.**

As you know, Section 1842(n) of the Social Security Act provides that

If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment **does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test**, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

The bold language clearly limits applicability of the rule to situations where the test is neither performed nor supervised by the physician or a physician with whom the physician shares a practice. Through your regulatory authority, at 42 C.F.R. 410.32, you created three levels of supervision for diagnostic tests. The definition of general supervision states that “the physician's presence is not required during the performance of the procedure.” If a physician (or someone with whom the physician shares a practice) is providing general supervision to a lab test, imaging, or other diagnostic test done offsite, the anti-markup statute does not apply. To the extent the new rule establishes additional requirements, it is inconsistent with the statute. In particular, the requirement that the physician “provides the full range of services” in the building is inconsistent with the statute. In short, the statute does not permit you to require a physician's presence unless that presence is necessary to supervise the test.

## **2. Even if the rule did not exceed the statutory authority, the rule unfairly penalizes organizations that provide diagnostic services in a free-standing location.**

Many clinics have space designated for diagnostic tests. (In fact, the final rule does not define “space” but some tests, such as MRIs, MUST be performed in special space for safety reasons. One could interpret the rule as requiring physicians to provide services in the room with the MRI, a practical impossibility.) Under the final rule, the organization is treated as if it is purchasing the test from its own employed technician. It is hard to understand what policy is advanced by the rule. Imagine two clinics. Both pay an MRI technician \$75,000 a year, or about \$1500/week, or \$300/day. The technician does about 15 scans a day. The only difference between the two clinics is that one clinic provides the full range of its services in one building, the other has a building designated exclusively for diagnostic services. Under the new rule, the first clinic may bill the full Medicare fee schedule, around \$450. The second clinic may only bill Medicare \$20 for a scan. No policy or logic underlies this dramatic reimbursement distinction. In both cases, the clinic is responsible for the cost of all overhead, including purchasing the equipment, and is responsible for supervising the tests. The services are being provided by employees. There is no reason to characterize the services provided at a centralized location as “purchased.” It is disingenuous to claim that a clinic is purchasing services from its own employees.

The new rule causes the clinic to lose significant money on each test. These are services provided by our employees, under our supervision. There is no reason to characterize these tests as “purchased.” Preventing a clinic from recovering its overhead costs creates an affirmative disincentive to provide care to Medicare patients.

**3. The statute only applies to diagnostic tests covered under 1861(s)(3). Interpretations are physician services covered under 1861(s)(1). Therefore, the anti-markup statute does not apply to interpretations.**

In recent rulemaking, CMS has gone to some lengths to emphasize that the various items listed under 1861(s) of the social security Act are different benefits. In your September 5<sup>th</sup> Stark III final rule, CMS stated that if a service was covered by one of the 1861(s) benefits, you will not permit the service to be provided “incident to” a physician’s services. CMS used that rationale to justify its refusal to pay for diagnostic tests as “incident to” a physician’s services.

“Diagnostic tests” are covered under 1861(s)(3), a separate benefit from 1861(s)(1), which covers physician services. The anti-markup statute refers only to “diagnostic tests,” not to “physician services.” CMS’ assertion that perhaps the omission was inadvertent is disingenuous. If Congress had meant to include the term “physician services” in the statute, it was free to do so over the ensuing 20 years. CMS does not have the authority to disregard the statute and combine 1861(s)(3) and 1861(s)(1), particularly given that CMS’ other interpretations have highlighted the distinction between those sections.

**4. A clinic should not be deemed to be “purchasing” an interpretation from its own employee simply because the employee is not in the main clinic space.**

We do not understand the argument that a clinic can “purchase” services from its own employees. Electronic communication makes it relatively easy for physicians to provide interpretive services offsite, whether at home, at space leased from a hospital or in another location. In many instances, patient care is improved by this capability; in the middle of the night it may be faster for a physician to do an interpretation from home than to come into the office.

There is no reason that the clinic should receive lower reimbursement based entirely on the location of physician when s/he performs the exam. The clinic is still incurring all of the overhead costs associated with the scan. (The site of service differential for services provided in the hospital is clearly distinguishable. There the hospital is incurring some of the overhead. For services provided at a physician’s home, the clinic is still fully responsible for the full overhead cost.) Limiting the clinic’s reimbursement to the amount billed by the physician prevents the clinic from recovering any of its overhead costs. Ironically, the new rule prevents the clinic from recouping the cost of acquiring the equipment that permits the offsite interpretation. It is terrible policy to penalize clinics willing to spend the money to improve patient care. The new rule also would prevent us from recovering any of the other basic costs of clinic operation including scheduling the appointment, preparing the report and having staff available to answer calls. In most clinics, overhead costs constitute approximately half of the total clinic revenue. The rule prevents clinics from recovering those costs when interpretations are done at the physician’s home, or at space devoted exclusively to providing interpretations.

I hope that you will carefully consider these comments and revise the rule so that it is consistent with the statute. Thank you for your time.

Sincerely,

Gil Irely, CEO  
Cedar Valley Medical Specialists, P.C.

**Submitter :** Dr. CHRISTOPHER KOPP  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-246-Attach-1.PDF

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## FOUNDING INDIVIDUAL MEMBERS

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James A. Turacki, M.D.

Robert G. Wagner, M.D.

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

Dear Administrator Weems:

I am a urologist who practices in a large practice in Western New York. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

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The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,

Richard N. Gilbert, M.D.

**Submitter :** Mr. Step Wirth  
**Organization :** Page, Wolfberg & Wirth, LLC  
**Category :** Attorney/Law Firm

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

See attachment

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

Ambulance Signature Rules (42 CFR Section 424.36)

CMS-1385-FC-247-Attach-1.PDF

CMS-1385-FC-247-Attach-2.PDF

**PAGE, WOLFBERG & WIRTH LLC**  
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○ MEMBERS, PENNSYLVANIA BAR  
Δ MEMBER, NEW YORK BAR

December 31, 2007

*VIA FIRST CLASS MAIL AND ELECTRONIC SUBMISSION*  
([david.walczak@cms.hhs.gov](mailto:david.walczak@cms.hhs.gov) and <http://www.cms.hhs.gov/eRulemaking>)

Kerry N. Weems, Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
Attention: CMS-1541-P  
Box 8012  
Baltimore, Maryland 21244-8012

**Re: 42 CFR Parts 409, 410, et al., Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemptions for Computer-Generated Facsimile Transmissions.**

Ladies and Gentlemen:

We are submitting comments regarding the above-referenced Final Rule with respect to the changes to 42 CFR Section 424.36, Beneficiary Signatures for Ambulance Transport Services. We respectfully request CMS to withdraw the Final Rule changes to this section until further input can be obtained from the ambulance industry and the full impact of these changes can be fully assessed. We also suggest that the requirement that ambulance services obtain patient or surrogate signature be eliminated completely. CMS had good intentions in its creation of an alternative to the general signature requirements for "emergency ambulance transport services" but this alternative will create significant added paperwork burdens on ambulance suppliers and providers, as well as take valuable time away from hospital personnel to sign new forms that must be created by the ambulance services to comport with the new exception.

### Brief Overview of Our Firm

Page, Wolfberg & Wirth, LLC is a law firm with a practice limited to the representation of ambulance services and emergency medical services (EMS) agencies. We represent over 800 ambulance services across the United States in the nonprofit, for-profit and public sectors. We also represent many EMS billing companies and other organizations which serve the nation's ambulance industry. Medicare compliance and reimbursement issues constitute the predominant part of our practice. In addition, we are regular columnists and contributing authors in many of the national ambulance industry publications and the attorneys and consultants of our firm collectively give approximately 100 presentations every year on issues of concern to the industry, including Medicare compliance and reimbursement. Our founding partners have also been active EMTs, paramedics and ambulance service administrators over the years.

We have conducted several audioconferences on the Final Rule signature requirements. (Go to [www.pwwemslaw.com](http://www.pwwemslaw.com) for an overview of these conferences). Through these audioconferences (in which over 700 ambulance services participated) and our contact with thousands of ambulance services nationwide through our listserve, we have received hundreds of inquiries from ambulance services around the country that are confused by the Final Rule and are unclear in its application.

### Comments to the Final Rule

#### 1) Ambulance Service Representatives Should Be Permitted to Sign the Claim When Other Signers Are Not Immediately Available To Sign

We believe that CMS should permit a representative of the ambulance supplier or provider to sign the claim form when: 1) the beneficiary is physically or mentally incapable of signing, and 2) none of the other approved surrogates are immediately available to sign.

In the comments to the final rule CMS states that it will no longer accept claims that are not signed by either the beneficiary or an authorized signer except in situations involving emergency ambulance transports. This is contrary to guidance that CMS has previously issued which does permit the ambulance service representative to sign when others are not immediately available. It also does not recognize the difficult situation that ambulance services are in when it comes to getting any signatures.

Ambulance services are unlike any other type of health care organization. Ambulance personnel are only with the patient for a very brief period of time and there are usually only two ambulance personnel assigned to an ambulance. They must focus their efforts on patient monitoring and treatment of the patient. They do not have the luxury of having a controlled environment in which to operate nor do they have support

personnel who could readily obtain signatures by walking down the hall a time later. To place the same signature burdens on ambulance services as is placed on other health care facilities does not take into account the unique nature of ambulance service delivery and the difficult challenges that ambulance service personnel face with every patient encounter.

It is in cases where there is an incapacitated beneficiary with nobody available to sign on his or her behalf that poses beneficiary signature problems. Currently, the language of 42 CFR §424.36(b) (5) indicates that a “representative of the provider” is permitted to sign on behalf of the beneficiary “if the beneficiary is physically or mentally incapable of signing the claim.” Ambulance suppliers could clearly fit within this particular exception already carved out in the regulation concerning beneficiary signature requirements. CMS could easily specify that the term “provider” as used in this section is clearly intended to mean all “Medicare providers” including ambulance services that are both suppliers and providers. Alternatively, CMS could just as easily add the word “supplier” to 424.36(b)(5), instead of advancing the more stringent interpretation in the commentary to the Final Rule.

Further, the Medicare Manuals have addressed situations where the beneficiary is unable to sign. Specifically, in cases where the “enrollee [is] physically or mentally unable to transact business and full documentation is supplied that the enrollee has no one else to sign on his behalf: The physician, supplier, or clinic may sign.” (See *e.g.* CMS Manual 100-4 (“Medicare Claims Processing Manual”), Chapter 1, Section 50.1.6 “When Beneficiary Statement is Not Required for Physician/Supplier Claim,” subsection A “Enrollee Signature Requirements.”) Ambulance services have routinely relied upon this language, which specifically grants the ambulance service provider the authority to sign “on behalf of the patient” as a “surrogate,” provided that there is adequate documentation showing that the beneficiary was unable to sign for him or herself, and that there was nobody else available to sign on the beneficiary’s behalf. Ambulance providers routinely document this information and sign on behalf of the beneficiary, in accordance with the guidance outlined in the Medicare Manual.

The comments to the final rule outline several conditions that must first be established. First, the beneficiary must be physically or mentally incapable of signing at the time of service when determining whether a substitute signature is required. This is an accurate portrayal of the current requirements of the regulation, as adopted in the Medicare Manuals, and as currently practiced by the ambulance industry. Ambulance services currently take steps to obtain a “surrogate signature” in situations where it is documented that the beneficiary is unable to sign for his or herself due to physical or mental constraints. In accordance with the Medicare Manual an appropriate surrogate signature can include a representative of the ambulance service. Second, none of the parties listed in 42 CFR § 424.36(b) (1)-(5) must be available to sign. As outlined above, we feel that any ambulance service that is a *supplier or provider* of ambulance service is is

a Medicare “provider” permitted to sign on behalf of the beneficiary. So there is no reason to create a new portion of the rule to specifically address situations where the beneficiary is unable to sign with specific reference to ambulance transports.

2) The Requirements to Meet the Exception for Emergency Ambulance Transports Are Unclear and Are Burdensome to Both Ambulance Service and Hospital Personnel

The Final Rule creates an exception to the signature rule for “emergency ambulance transports.” (Section 424.36 (b) (6)). Yet CMS does not define the phrase and it is not one of the standard definitions under Ambulance Fee Schedule. There is no commentary to the rule that explains the phrase either. We can only presume what CMS intended here. We would hope that CMS would consider the phrase “emergency ambulance transport” to encompass any claim that fits the definition for “emergency response” under the fee schedule. That would include claims submitted with HCPCS codes A0427 (ALS 1-E), A0429 (BLS-E), A0432 (Paramedic Intercept), A0430 (Air-Fixed Wing), A0431 (Air-Rotary Wing) and emergency claims under A0433 (ALS-2) and A0434 (Specialty Care Transport).

The Final Rule also imposes three specific “documentation” requirements: 1) a contemporaneous statement made by an ambulance employee present during the trip; 2) the date and time the beneficiary was transported and the name of the location at which the beneficiary was received; 3) a signed contemporaneous statement from a representative of the facility that received the beneficiary. Collectively, these “documentation” requirements create an unnecessary and onerous burden on both the ambulance service and the receiving facility (presumably a hospital), and, in light of the above, are actually unnecessary.

The Final Rule does offer an alternative to the requirement of the signed contemporaneous statement from a representative of the facility that received the patient. That alternative allows for certain “secondary forms of verification.” But obtaining these secondary forms of verification also places a significant burden on ambulance services to obtain and store additional records that have not been required in the past.

There is no rational reason that a “contemporaneous statement” of the ambulance service be required. Because a representative of the “provider” is already permitted to, and in fact does, sign the “Assignment of Benefits” Form (used by the ambulance service to capture the beneficiary’s signature) on behalf of the beneficiary, there is no reason to require some “contemporaneous statement.” The Assignment of Benefits Form includes a date, and most ambulance services (when signing on behalf of a beneficiary) will reference the reason that the beneficiary was unable to sign for him or herself. Further, information included on the “narrative” portion of the “patient care report” or “pre-hospital care report” (“PCR”) (which is completed by the ambulance personnel) will document the condition of the beneficiary that indicates why he or she was unable to sign

for him or herself. If a beneficiary signature was not obtained, and the beneficiary was unable to sign, and nobody else was available, and such facts are documented, a “representative” of the ambulance service typically signs the Assignment of Benefits Form on behalf of the beneficiary. To require a “contemporaneous statement” from the ambulance service, as signed by the ambulance service personnel actually on the scene indicates that an employee signing the “Assignment of Benefits” Form (as permitted by the Medicare Manual in interpreting the present regulation) would be inadequate. There is no reason under the current regulations why this should be the case.

Similarly, there is no reason that the date and time the beneficiary was transported, and the location of the receiving facility must be part of any contemporaneous statement. This information is clearly part of either the “Assignment of Benefits” Form, or included on the PCR already. The PCR records the date of the transport, the time of the dispatch, the time of arrival on scene with the beneficiary, and the time of arrival at the receiving facility, as well as the name of the receiving facility. To have to repeat all of this information on a “contemporaneous statement” would be time consuming, and would merely be a repetition of information already captured at other locations on the ambulance documentation.

Finally, there is absolutely no reason at all to require a signed contemporaneous statement from a representative of the receiving facility. This places a significant burden on the receiving hospital. The hospital personnel are already dealing with registering the patient, adhering to federal laws such as EMTALA, trying to treat and triage the patient, receiving clinical documentation from the ambulance staff, and should not have to, nor be required to complete a “contemporaneous statement” to outline that a particular beneficiary was in fact incapable of signing for him or herself. The hospital has no incentive to complete this statement and hospital personnel may refuse to sign a statement under the erroneously belief that personal or facility financial responsibility will accrue.

The need for a hospital employee to sign a statement confirming that the patient was in fact received and that the beneficiary was incapable of signing also implies that the ambulance services are not trusted. Ambulance service personnel are trained to administer pre-hospital emergency care. Consequentially, as part of their training, and through patient evaluation, the ambulance personnel are able to determine if the patient is capable of signing. For a hospital employee to have to “verify” this finding, and to confirm that the beneficiary was actually received at the hospital greatly calls into the question the knowledge, skill, and integrity of the ambulance service personnel, a person who has dedicated his or her life to providing emergency services to the community and serving the Medicare beneficiaries that CMS strives to protect.

3) The Requirement That Ambulance Services Obtain Patient or Surrogate Signatures Should be Eliminated

We believe the rationale behind obtaining a patient signature in the first place makes the requirement unnecessary at this time, and that the requirement should be abandoned. One purpose of obtaining a beneficiary signature is for the beneficiary to authorize an "assignment of benefits." However, in accordance with 42 CFR §414.605(b) all ambulance claims are automatically submitted on an "assignment related basis" under the concept known as "mandatory assignment." This regulatory requirement renders obtaining the beneficiary's signature to "assign benefits" to the ambulance obsolete.

Also, though, the beneficiary signature is used as an authorization for the release of records to CMS. However, in accordance with HIPAA at 45 CFR §164.506(c) (3), a health care provider is authorized to release health care records for "payment" purposes. A provider, such as an ambulance service, is clearly permitted, and in fact authorized, to release beneficiary information, without the beneficiary's permission, for payment purposes. Since CMS serves as the payer of the ambulance claims, release of any beneficiary records is clearly permitted, if not required, for payment purposes, and should not require a beneficiary signature. In short, therefore, requiring the beneficiary's signature for ambulance transports serves no true purpose.

With the Final Rule, CMS seemingly creates a new requirement never seen before with respect to signatures: that the signature of the patient and receiving hospital personnel is essential to *verify that ambulance service was actually provided*. This has never been the purpose of patient authorization signatures in the past, and there is no need to require it now. The verification of ambulance transport could be obtained by CMS and its contractors by matching ambulance records to hospital records. The burden should not be placed on ambulance services --- with the limited time they spend with patients and the limited staffing they have --- to obtain verification and records from the hospital to verify the provision of ambulance service. The ambulance service already provides this verification with the submission of the claim in the first place, under the penalties of the False Claims Act and other laws. Why create a new requirement that is not necessary and that creates an added burden on ambulance services?

\* \* \*

We appreciate the opportunity to offer our comments on the Final Rule.

Very truly yours,

Stephen R. Wirth

Douglas M. Wolfberg

**Submitter :** Dr. CARLO PERFETTO  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

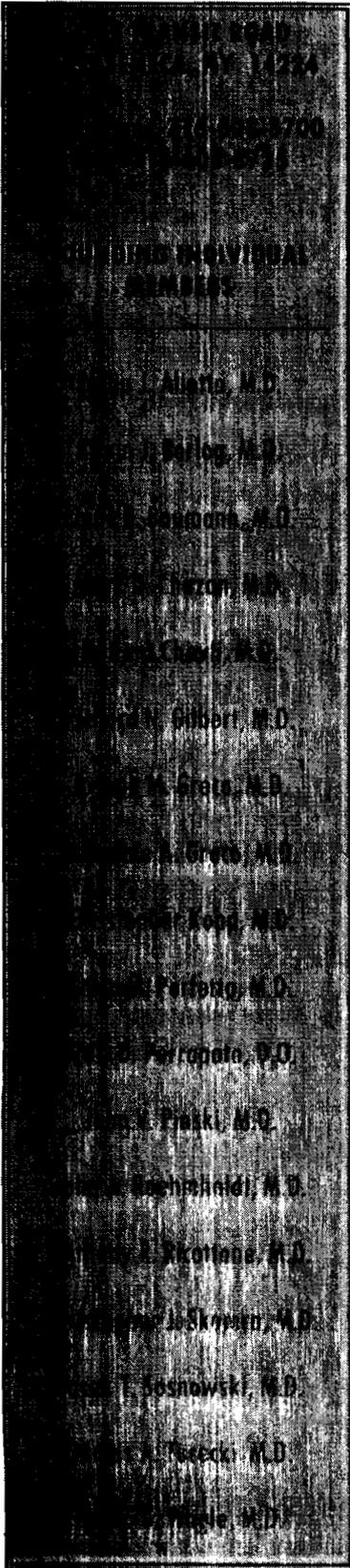
GENERAL

SEE ATTACHMENT

CMS-1385-FC-248-Attach-1.PDF

#248

# UROLOGIC IPA OF NEW YORK, LLC



December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

Dear Administrator Weems:

I am a urologist who practices in a large practice in Western New York. I am writing to comment on the changes to the anti-markup rule that were published in the Physician Fee Schedule on November 27, 2007 that concern the purchased diagnostic testing rules.

The final rule imposes an anti-markup provision on the technical and professional components of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the technical or professional component is purchased from an "outside supplier" or if it is performed at a site other than the office of the billing physician or other supplier. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on where the test is furnished. Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," i.e., the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

When the anti-markup rule applies to a diagnostic test, the amount of payment is affected by requiring that a "net charge" be calculated. CMS has given little guidance with respect to calculating the "net charge" when a service is provided by the employed technologists and physicians of a practice where those individuals are not compensated based on a per test basis. In addition, the CMS rules require that the "net charge" be calculated without regard to any overhead, including the cost of equipment or leased space.

Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, after relying upon CMS guidance with respect to the physician self-referral laws and regulations—will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients if the billing medical practice does not have a full service office where the test is provided. These changes will have a serious impact on geographically disbursed practices that have centralized services in a facility that is not their main location.

The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,

Carlo M. Perfetto, M.D.

**Submitter :** Dr. JOHN ROEHMHOLDT  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-249-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

2732 TRANSIT ROAD  
WEST SENECA, NY 14224

Telephone: 716-608-8700  
Fax: 716-608-8725

## FOUNDING INDIVIDUAL MEMBERS

Philip J. Aliotta, M.D.

Kevin J. Barlog, M.D.

Louis R. Baumann, M.D.

Mark D. Chazan, M.D.

K. Kent Chevli, M.D.

Richard N. Gilbert, M.D.

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Pasquale A. Greco, M.D.

Christopher Kopp, M.D.

Carlo M. Perfetto, M.D.

Scott D. Ferrapato, D.D.

John V. Piraki, M.D.

John S. Roehmholdt, M.D.

Anthony A. Ricottano, M.D.

Christopher J. Skrimco, M.D.

Thomas T. Sosnowski, M.D.

James A. Turecki, M.D.

William D. Wagle, M.D.

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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Thank you for your consideration,



John Roehmholdt, M.D.

**Submitter :** Dr. ANTHONY RICOTTONE  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-250-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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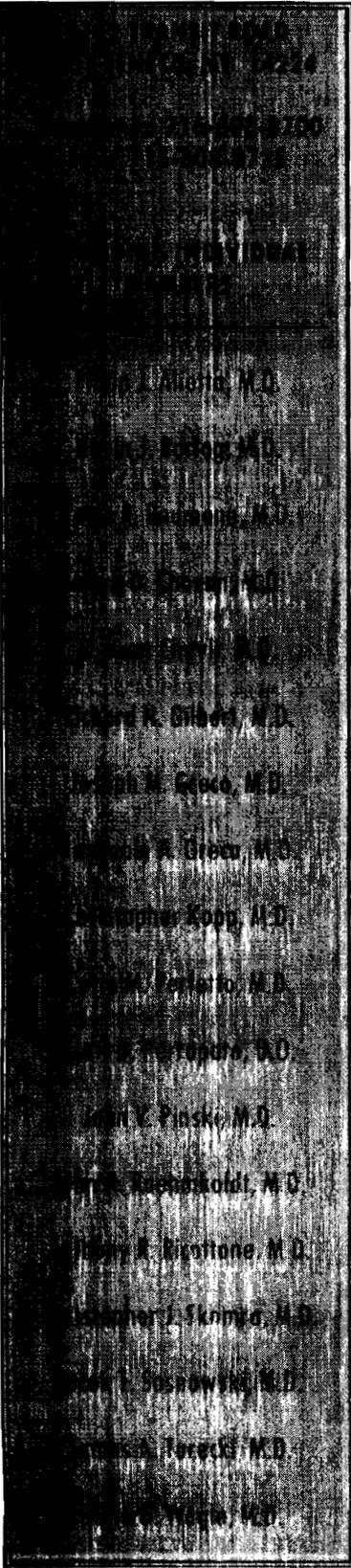
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Thank you for your consideration,



Anthony R. Ricottone, M.D.



**Submitter :** Dr. CHRISTOPHER SKOMRA  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

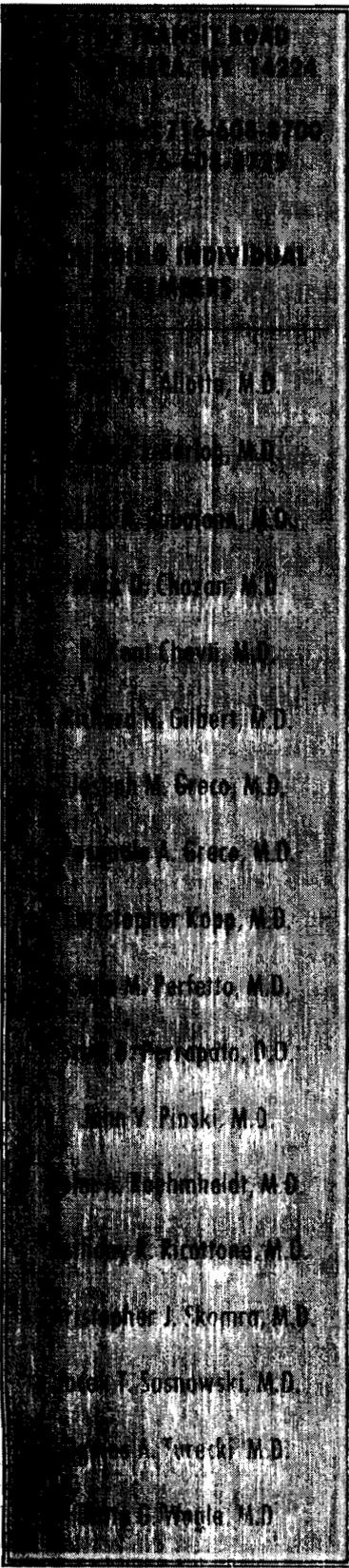
**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-251-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC



December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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Thank you for your consideration,

Christopher J. Skomra, M.D.

**Submitter :** Dr. JOHN PINSKI  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-252-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC

2792 TRANSIT ROAD  
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Telephone: 716-608-8700  
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### FOUNDING INDIVIDUAL MEMBERS

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John A. Rosenfeldt, M.D.

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David T. Szczykowski, M.D.

Thomas A. Turecki, M.D.

William P. Wagle, M.D.

December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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Thank you for your consideration,



John V. Pinski, M.D.

**Submitter :** Dr. DATTA WAGLE  
**Organization :** UROLOGIC IPA OF NEW YORK, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

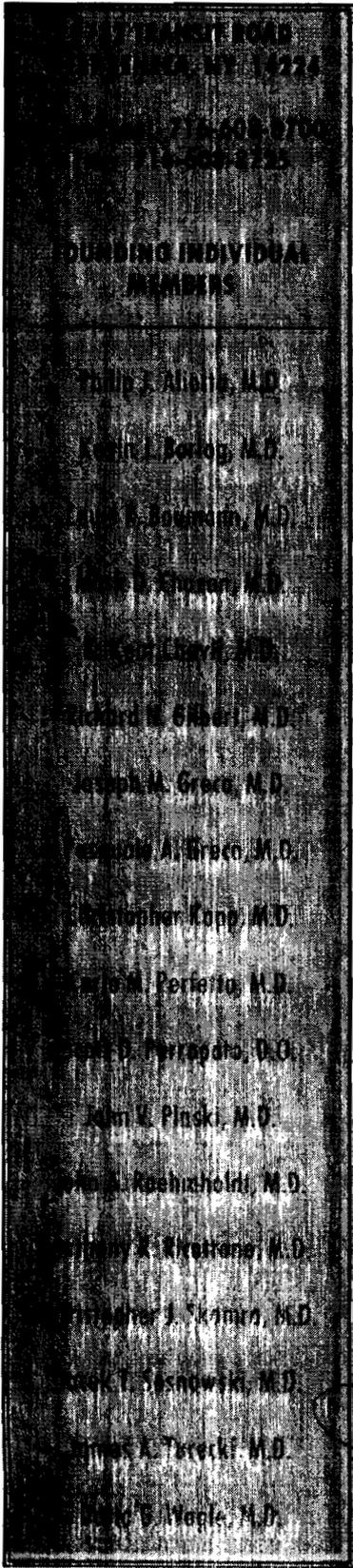
**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-253-Attach-1.PDF

# UROLOGIC IPA OF NEW YORK, LLC



December 31, 2007

Kerry Weems  
 Acting Administrator  
 Centers for Medicare and Medicaid Services  
 Department of Health and Human Services  
 Attention: CMS-1385-FC  
 P.O. Box 8020  
 Baltimore, MD 21244-8020

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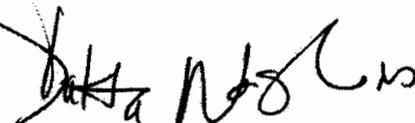
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Thank you for your consideration,

  
 Datta G. Wagle, M.D.

**Submitter :** Dr. LAURENCE DONAHUE  
**Organization :** UROLOGY ASSOCIATES OF ROCHESTER  
**Category :** Physician

**Date:** 12/31/2007

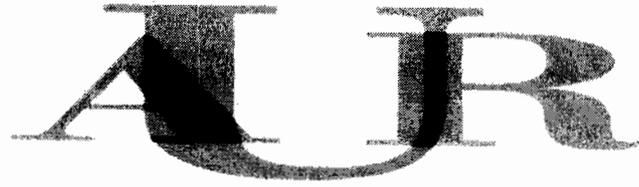
**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-254-Attach-1.PDF



**UROLOGY ASSOCIATES OF ROCHESTER**

**David P. Dever, M.D. • Laurence A. Donahue, M.D. • Beng Jit Tan, M.D., PhD • Brian D. Adcock, RPA-C • Paul F. Scheib, RPA-C**

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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995 Senator Keating Blvd.  
1415 Portland Avenue  
50 South Street  
422 North Main Street

Suite 330  
Suite 220

Rochester, New York 14618  
Rochester, New York 14621  
Geneseo, New York 14454  
Warsaw, New York 14569

585-232-2980  
585-266-4110  
585-243-2560  
585-786-2090

Fax 585-232-6522  
Fax 585-266-2523  
Fax 585-232-6522  
Fax 585-786-3990

E-Mail [uar@maximweb.com](mailto:uar@maximweb.com) [www.urologyrochester.com](http://www.urologyrochester.com)

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Thank you for your consideration,

A handwritten signature in cursive script that reads "Laurence A. Donahue, M.D." The signature is written in black ink and is positioned above the typed name.

Laurence A. Donahue, M.D.

**Submitter :** Dr. DAVID DEVER  
**Organization :** UROLOGY ASSOCIATES OF ROCHESTER  
**Category :** Physician

**Date:** 12/31/2007

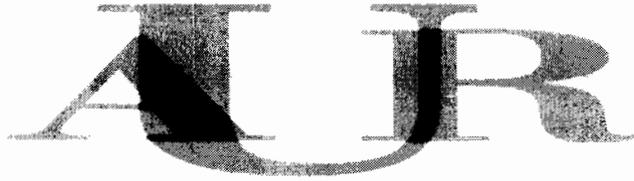
**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-255-Attach-1.PDF



## UROLOGY ASSOCIATES OF ROCHESTER

David P. Dever, M.D. • Laurence A. Donahue, M.D. • Beng Jit Tan, M.D., PhD • Brian D. Adcock, RPA-C • Paul E. Scheib, RPA-C

Kerry Weems  
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995 Senator Keating Blvd.  
1415 Portland Avenue  
50 South Street  
422 North Main Street

Suite 330  
Suite 220

Rochester, New York 14618  
Rochester, New York 14621  
Geneseo, New York 14454  
Warsaw, New York 14569

585-232-2980  
585-266-4110  
585-243-2560  
585-786-2090

Fax 585-232-6522  
Fax 585-266-2523  
Fax 585-232-6522  
Fax 585-786-3990

E-Mail [uar@maximweb.com](mailto:uar@maximweb.com) [www.urologyrochester.com](http://www.urologyrochester.com)

geographically disbursed practices that have centralized services in a facility that is not their main location.

The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,

A handwritten signature in black ink, appearing to read "D. Dever", with a stylized flourish at the end.

David P. Dever, M.D.

**Submitter :** Dr. PASQUALE GRECO  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-256-Attach-1.PDF

# WESTERN NEW YORK Urology Associates, LLC

Adult and Pediatric Urology  
www.wnyurology.com

Kevin J. Barlog, M.D., FACS  
Louis R. Baumann, M.D., FACS  
K. Kent Chevli, M.D., FACS  
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Pamela M. Gandy, R.N., F.N.P.  
Emily A. Levandusky, RPA-C  
James P. Rew, RPA-C

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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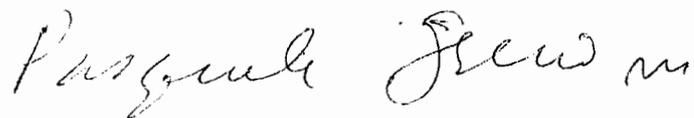
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Thank you for your consideration,

A handwritten signature in cursive script that reads "Pasquale Greco M.D." The signature is written in black ink and is positioned above the printed name.

Pasquale A. Greco, M.D.

**Submitter :** Dr. KEVIN BARLOG

**Date:** 12/31/2007

**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENTS

CMS-1385-FC-257-Attach-1.PDF

# WESTERN NEW YORK Urology Associates, LLC

Adult and Pediatric Urology  
www.wnyurology.com

Kevin J. Barlog, M.D., FACS  
Louis R. Baumann, M.D., FACS  
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Baltimore, MD 21244-8020

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Orchard Park, NY 14221  
PH: 716-617-2273  
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Jamestown  
103 Allen Street  
Jamestown, NY 14701  
PH: 716-488-1851  
FX: 716-484-2972

Brierwood Medical Center  
3040 Amsdell Road  
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Thank you for your consideration,

A handwritten signature in cursive script that reads "Kevin Barlog". The signature is written in black ink and is positioned above the printed name.

Kevin J. Barlog, M.D.

**Submitter :** Dr. KENT CHEVLI

**Date:** 12/31/2007

**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-258-Attach-1.PDF

# WESTERN NEW YORK Urology Associates, LLC

Adult and Pediatric Urology  
www.wnyurology.com

Kevin J. Barlog, M.D., FACS  
Louis R. Baumann, M.D., FACS  
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Department of Health and Human Services  
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Kent Chevli, M.D.

**Submitter :** Dr. RICHARD GILBERT  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-259-Attach-1.PDF

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Adult and Pediatric Urology  
www.wnyurology.com

Kevin J. Barlog, M.D., FACS  
Louis R. Baumann, M.D., FACS  
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Joseph M. Greco, M.D., FACS  
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Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
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P.O. Box 8020  
Baltimore, MD 21244-8020

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Thank you for your consideration,

A handwritten signature in black ink, appearing to read "Richard N. Gilbert". The signature is written in a cursive style with a large initial "R" and "G".

Richard N. Gilbert, M.D.

**Submitter :** Dr. JOSEPH GRECO  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

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Thank you for your consideration,

A handwritten signature in black ink, appearing to read "J. Greco". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

Joseph M. Greco, M.D.

**Submitter :** Dr. CHRISTOPHER SKOMRA  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician  
**Issue Areas/Comments**

**Date:** 12/31/2007

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-261-Attach-1.PDF

# WESTERN NEW YORK Urology Associates, LLC

Adult and Pediatric Urology  
www.wnyurology.com

Kevin J. Barlog, M.D., FACS  
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Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
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Thank you for your consideration,

A handwritten signature in cursive script that reads "Christopher Skomra, M.D." The signature is written in dark ink and is positioned above the printed name.

Christopher J. Skomra, M.D.

**Submitter :** Dr. JOHN ROEHMHOLDT  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-262-Attach-1.PDF

# WESTERN NEW YORK Urology Associates, LLC

Adult and Pediatric Urology  
www.wnyurology.com

Kevin J. Barlog, M.D., FACS  
Louis R. Baumann, M.D., FACS  
K. Kent Chevli, M.D., FACS  
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Pamela M. Gandy, R.N., F.N.P.  
Emily A. Levandusky, RPA-C  
James P. Rew, RPA-C

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

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Thank you for your consideration,

A handwritten signature in cursive script that reads "John Roehmholdt".

John M. Roehmholdt, M.D.

**Submitter :** Dr. PETER WALTER

**Date:** 12/31/2007

**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

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Thank you for your consideration,

A handwritten signature in black ink, appearing to read 'P. J. Walter'.

Peter J. Walter, M.D.

**Submitter :** Dr. ICHABOD JUNG  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-1385-FC-264-Attach-1.PDF

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Department of Health and Human Services  
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Ichabod Jung, M.D.

**Submitter :** Dr. RYAN WHITE

**Date:** 12/31/2007

**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC

**Category :** Physician

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-265-Attach-1.PDF

#265

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Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
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P.O. Box 8020  
Baltimore, MD 21244-8020

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Thank you for your consideration,

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Ryan G. White, M.D.

**Submitter :** Dr. LOUIS BAUMANN  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-266-Attach-1.PDF

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Thank you for your consideration,

A handwritten signature in cursive script that reads "Louis Baumann". The signature is written in black ink and is positioned above the printed name.

Louis R. Baumann, M.D.

**Submitter :** Dr. CHRISTOPHER KOPP

**Date:** 12/31/2007

**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC

**Category :** Physician

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-267-Attach-1.PDF

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Adult and Pediatric Urology  
www.wnyurology.com

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When the anti-markup rule applies to a diagnostic test, the amount of payment is affected by requiring that a "net charge" be calculated. CMS has given little guidance with respect to calculating the "net charge" when a service is provided by the employed technologists and physicians of a practice where those individuals are not compensated based on a per test basis. In addition, the CMS rules require that the "net charge" be calculated without regard to any overhead, including the cost of equipment or leased space.

Finally, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices, after relying upon CMS guidance with respect to the physician self-referral laws and regulations—will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its patients if the billing medical practice does not have a full service office where the test is provided. These changes will have a serious impact on

geographically disbursed practices that have centralized services in a facility that is not their main location.

The sweeping changes to the anti-markup rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. I respectfully request that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries and delay the implementation of the rule until CMS has had time to understand the full impact of these rules.

Thank you for your consideration,

A handwritten signature in cursive script, appearing to read "Christopher Kopp".

Christopher Kopp, M.D.

**Submitter :** Dr. CARLO PERFETTO

**Date:** 12/31/2007

**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC

**Category :** Physician

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-268-Attach-1.PDF

# WESTERN NEW YORK Urology Associates, LLC

Adult and Pediatric Urology  
www.wnyurology.com

Kevin J. Barlog, M.D., FACS  
Louis R. Baumann, M.D., FACS  
K. Kent Chevli, M.D., FACS  
Richard N. Gilbert, M.D., FACS  
Joseph M. Greco, M.D., FACS  
Pasquale A. Greco, M.D.  
Ichabod Jung, M.D., FACS  
Christopher Kopp, M.D., FACS  
Carlo M. Peretto, M.D.  
Scott D. Perrapato, D.O., FACOS  
Anthony R. Ricottone, M.D., FACS

John M. Roehmholdt, M.D., FACS  
Christopher J. Skomra, M.D., FACS  
Peter J. Walter, M.D., FACS  
Ryan G. White, M.D., FACS  
Shannon M. Bunch, RPA-C  
Peter A. Coggiola, R.N., N.P.  
Brian C. Crotzer, RPA-C  
Pamela M. Gandy, R.N., F.N.P.  
Emily A. Levandusky, RPA-C  
James P. Rew, RPA-C

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

Dear Administrator Weems:

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**Windsong Medical Park**  
55 Spindrift Drive, Suite 240  
Williamsville, NY 14221  
PH: 716-631-9600  
FX: 716-631-9251

**Sterling Park**  
500 Sterling Drive  
Orchard Park, NY 14127  
PH: 716-677-2273  
FX: 716-677-2256

**Jamestown**  
103 Allen Street  
Jamestown, NY 14701  
PH: 716-488-1851  
FX: 716-484-2972

**Brierwood Medical Center**  
3040 Amsdell Road  
Hamburg, NY 14075  
PH: 716-677-2273  
FX: 716-677-2256

**City Centre**  
36 Ellicott Street, Suite 2  
Batavia, NY 14020  
PH: 585-344-4600  
FX: 585-344-0877

**Northern Pennsylvania**  
1 Timberview Lane  
Russell, PA 16345  
PH: 814-757-8003  
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Thank you for your consideration,

A handwritten signature in black ink, appearing to read "Carlo Perfetto". The signature is written in a cursive style with a large initial "C".

Carlo M. Perfetto, M.D.

**Submitter :** Dr. ANTHONY RICOTTONE  
**Organization :** WESTERN NEW YORK UROLOGY ASSOCIATES, LLC  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-FC-269-Attach-1.PDF

# WESTERN NEW YORK Urology Associates, LLC

Adult and Pediatric Urology  
www.wnyurology.com

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James P. Rew, RPA-C

Kerry Weems  
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Thank you for your consideration,

A handwritten signature in cursive script, appearing to read "Anthony R. Ricottone".

Anthony R. Ricottone, M.D.

Submitter :

Date: 12/31/2007

Organization : National Athletic Trainers' Association

Category : Other Health Care Professional

Issue Areas/Comments

**GENERAL**

GENERAL

The file attachment is not working will send email to D Shannon

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

To: DHHS CMS, Dorothy Shannon December 31, 2007

[www.cms.hhs.gov/eRulemaking](http://www.cms.hhs.gov/eRulemaking), [Dorothy.Shannon@cms.hhs.gov](mailto:Dorothy.Shannon@cms.hhs.gov)

Re: file code CMS-1385-FC

NATA is submitting these recommendations for consideration as suggested in Dorothy Shannon s email from December 18, 2007.

Application of Consistent Therapy Standards (1) Personnel Qualifications

When writing instructions in regard to CMS 1385 FC, NATA considers it necessary to clarify what constitutes athletic training services.

The CMS comments in 1385 FC state that athletic trainers will still be able to provide athletic training services in a hospital setting as long as they are not documented as physical therapy services.

Since there are no CMS guidelines or definitions for athletic training services, the pertinent guidelines and definitions from the professional association for athletic training, the NATA, should be utilized in a similar manner as CMS defers to the APTA for guidance on physical therapy.

What constitutes athletic training service?

Athletic Training Services include, but are not limited to:

- Risk Management and Injury Prevention
- Assessment and Evaluation of Injuries
- Acute Care of Injury and Illness
- Therapeutic Modalities, Therapeutic Exercise
- Nutritional Aspects of Injury, Illness, and Wellness
- Psychosocial referral
- Health Care Administration
- Educational Programs and workshops

When providing these services athletic trainers use CPT codes from the physical medicine section of the CPT manual as well as other codes as allowed by state practice acts.

The athletic trainers proficiencies do not change depending on their location at the time of treatment.

Should you have any questions, please contact me. Thanks for considering the above.

Patty Ellis  
National Manager of Markets and Revenue  
National Athletic Trainers Association  
2952 Stemmons Freeway Dallas, TX 75247  
972-532-8833 [patty@nata.org](mailto:patty@nata.org)

- 1 National Athletic Trainers Association Education Council  
<http://nataec.org/AcademicPrograms/ProfessionalEducationentrylevel/Competencies/tabid/79/Default.aspx>
- 2 CPT 2008 Professional Edition , American Medical Association.

**Submitter :** Edward Greissing

**Date:** 12/31/2007

**Organization :** sanofi-aventis

**Category :** Drug Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-1385-FC-271-Attach-1.DOC

#271

FILE:///ELECTRONIC%20COMMENTS/ELECTRONIC%20COMMENTS/E-Comments/Active%20Files/Missing%20file1.txt

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Dr. Hunter Sams  
**Organization :** Denver Dermatology  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Mohs surgery involves much more than surgery; included is removal, preparation, orientation, staining, and histopathologic analysis of tissue. Each specimen must be treated the same whether 2 or more surgical sites are done in the same day. Therefore, it should not be subject to the multiple surgical reduction rule. Thank you for your attention to this matter.

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

Mohs micrographic surgery 17311, 17312, 17313, 17314, and 17315

**Submitter :** Mr. Thomas Millward

**Date:** 12/31/2007

**Organization :** US Army (Ret)

**Category :** Individual

**Issue Areas/Comments**

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

My name is Tom Millward and I was diagnosed with Basal Cell Nevous Syndrome several years ago. Over the past 15 years I have had at least 115 Basal Cells removed with at least 50 of those removed using MOHS procedure. It is very beneficial for me to be able to let the doctor remove and repair more than one spot at a time!! This cuts down on healing time and also helps with less time missed from work, and also saves in Co-Pays. I also believe to have multiple MOHS procedures in one visit is a decision between the patient and the doctor!!!

Thanks

Tom Millward

millwardga@comcast.net

**Submitter :** Margaret Boiano

**Date:** 12/31/2007

**Organization :** VNUS Medical

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1385-FC-274-Attach-1.DOC

**Via Electronic**

Attention: **CMS-1385-FC; PE RVUs Methodology Section**  
Centers for Medicare and Medicaid Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850  
<http://www.cms.hhs.gov/eRulemaking>

**CMS-1385-FC-Revisions to the Physician Fee Schedule for Calendar Year 2008**

We would like to submit a PE RVU **correction error** comment to the Centers for Medicare and Medicaid Services (CMS) on the practice expense methodology for CPT code **36479**, an add-on code for CPT code 36478.

As stated in the last CMS final ruling *"If we have made errors, major or minor, in any part of our calculation of practice expense RVUs in this final rule, inform us as soon as possible so that we are able to correct them in the physician fee schedule correction notice. Any other revisions would have to be made in the next physician fee schedule rule."*

We believe that the CPT code 36479 had been miscalculated when it was first listed in **2005** on the NF PE RVUs, (please see 69 Fed. Reg. at 66,502) and due to the error, it has have been consistently misvalued since in the rulings and especially after the five year review.

**Based on CMS' 2005 final rule, it lists the Final PE RVUs for CPT Codes 36478-36479 as follows:**

Code	Description	Non-Facility PE RVUs	Facility PE RVUs
36478	Endovenous laser, First vein	46.77	2.53
36479	Endovenous laser, vein add-on	<b>7.99</b>	<b>1.14</b>

- As CMS correctly affirmed in the 2007 final ruling; laser ablation CPT codes 36478 practice costs are noticeably less and it should be also reflected in the add-on code 36479.
- Consequently, the values should **be lower** on the **add-on CPT code 36479 NF and Facility RVU values.**

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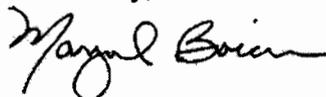
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- Therefore, CMS should make a correction to both the Non-facility and Facility PE RUV calculation values for CPT **36479** in the 2008 final ruling, so the **correct** values are reflected for 2008 and in the fully implementation for 2010.

Should you have any questions, please contact me at 408-360-7560 or Gail Daubert at 202-414.-9241.

Thank you very much for your consideration.

Sincerely,



Margaret Boiano  
Director of Reimbursement  
VNUS Medical Technologies, Inc.

CC: Pam West-CMS  
Rick Ensor-CMS

**Submitter :** Sonny Kimm

**Date:** 12/31/2007

**Organization :** Sonny Kimm

**Category :** Individual

**Issue Areas/Comments**

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

**Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007**

I oppose any legislation that would discourage my physician from completing my surgical treatment in one visit. I do not want my physician to be compelled to reschedule my subsequent treatments in order to be fully compensated for his work.

**Submitter :** Margaret Boiano

**Date:** 12/31/2007

**Organization :** VNUS Medical

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment

CMS-1385-FC-276-Attach-1.PDF

**Via Electronic**

Attention: **CMS-1385-FC; PE RVUs Methodology Section**  
Centers for Medicare and Medicaid Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
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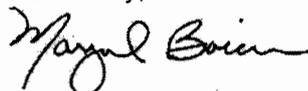
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Thank you very much for your consideration.

Sincerely,



Margaret Boiano  
Director of Reimbursement  
VNUS Medical Technologies, Inc.

CC: Pam West-CMS  
Rick Ensor-CMS

**Submitter :** Margaret Boiano  
**Organization :** VNUS Medical  
**Category :** Device Industry

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see PDF attachment- first attempt there was an error attaching.

CMS-1385-FC-277-Attach-1.PDF

**Submitter :** Mr. george gasparovic  
**Organization :** Pendleton Emergency Ambulance  
**Category :** Other Health Care Provider

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Pendleton Ambulance is a central Indiana non-profit volunteer group providing emergency medical care to approx. 20,000 people. The patient signature requirement, mandating signatures in all responses, will cause increased volunteer time & a negative financial impact. In cases of emergency the patient contact maybe a single event in which signatures & pursuit of one is illogical & burdensome. As we are submitting electronically with hard copy backup, when obtainable, the current requirements are adequate. Contact with the receiving hospital could give validity to any claim from an emergency service, if there is concern of fraud. Please suspend or vacate the proposed language, the proposed signature change adds nothing to patient care or ability of an organization to maintain quality care.

**Submitter :** Dr. Paul Schellhammer  
**Organization :** American Urological Association  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1385-FC-279-Attach-1.DOC

**Via Electronic**

Attention: **CMS-1385-FC; PE RVUs Methodology Section**  
Centers for Medicare and Medicaid Services  
Mail Stop C4-26-05  
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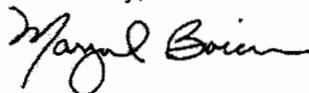
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Thank you very much for your consideration.

Sincerely,



Margaret Boiano  
Director of Reimbursement  
VNUS Medical Technologies, Inc.

CC: Pam West-CMS  
Rick Ensor-CMS

**Submitter :**

**Date:** 12/31/2007

**Organization :** Medical Group Management Association

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1385-FC-280-Attach-1.PDF



# American Urological Association

## BOARD OF DIRECTORS

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December 31, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

**Re: CMS-1385-FC: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008.**

Dear Administrator Weems:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments in response to the anti-markup rule published in the 2008 Medicare Physician Fee Schedule. We understand that the Centers for Medicare & Medicaid Services (CMS) has delayed certain portions of the anti-markup rule until January 1, 2009 in order to issue clarifying guidance or additional rulemaking about what constitutes the "office of the billing physician or other supplier." Nevertheless, the AUA urges CMS to take our comments into account as it prepares additional guidance or rulemaking on this issue, because if this new rule is implemented as drafted, it will severely disrupt physician practices throughout the country.

Such disruption will necessitate the dismantling of countless arrangements—arrangements that were carefully structured to meet existing regulations. As a result, patient care will be adversely affected, not only in terms of the *quality* of medical care, but also in terms of *access* to medical care. In addition, the AUA feels strongly that this new rule is not necessary to protect the Medicare program against the fraudulent or abusive arrangements it appears to address, particularly in light of the substantial laws already in place to address self-referrals and other potentially abusive practices. For the reasons set forth below, the AUA urges CMS to reconsider implementation of the final anti-markup rule and to the corresponding provisions in the reassignment and physician self-referral rules.



ANNUAL MEETING  
17-22 May 2008  
Orlando, Florida USA

[www.aua2008.org](http://www.aua2008.org)

### **CMS's Proposed Revisions to the Anti-Markup Rule**

In the Proposed 2008 Physician Fee Schedule, CMS proposed to “clarify” the anti-markup rule so that the anti-markup provision on the professional portion of a purchased diagnostic test would match the anti-markup provision already imposed on the technical component of such tests. In addition, CMS proposed to apply the anti-markup provision regardless of whether the billing entity purchased the technical or

professional component outright *or received a reassignment of the right to bill*. Prior to implementation of the final rule, as long as a test is not purchased, but properly re-assigned to the billing physician or physician group, the anti-markup provisions do not apply. The proposed rule determined the applicability of the anti-markup provision based on the employment status (full-time employee, part-time employee, or independent contractor) of the technologist and physician performing the test. Due to numerous comments questioning the feasibility of such a rule, CMS decided to finalize an anti-markup rule that is drastically different from—and as equally indefensible as—the proposed rule.

### **CMS's Finalized Revisions to the Anti-Markup Rule**

#### **“Office of Billing Physician or Other Supplier” Requirement**

The final rule imposes an anti-markup provision on the technical and professional components of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the technical or professional component is purchased from an “outside supplier” *or if it is performed at a site other than the office of the billing physician or other supplier*. This is a wholly different test than what was proposed. Rather than focusing on whether the test was purchased or not, the new rule applies the anti-markup provision simply based on *where the test is furnished*. Under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished “in the office of the billing physician or other supplier,” *i.e.*, the “space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally.”

#### **Calculation of Net Charge**

Under the final anti-markup rule, CMS limits the payment for a diagnostic test (both the technical and the professional components) that is either purchased from an outside supplier or performed at a site other than the office of the billing physician or other supplier to the lower of:

- (i) the performing supplier’s *net charge* to the billing physician or other supplier,
- (ii) the billing physician or other supplier’s actual charge, or
- (iii) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.

72 Fed. Reg. 66401 (November 27, 2007). The rule further restricts payment by requiring that the “net charge” be calculated “without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier.” *Id.*

The language of the regulation itself indicates that the “net charge” applies when there are two parties—the billing entity and the supplier:

The net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space *leased to the performing supplier* by or through the *billing physician or other supplier*.

42 C.F.R. §414.50(a)(2)(i) (emphasis added). The plain meaning of this language indicates that if the physician group is itself performing the test and has leased the space/equipment for its own use as a "centralized building," or in the "same building," but not the same office, then this portion of the rule should not apply and the physician group should be able to include overhead amounts for space and equipment in its "net charge." This is so because there is no lease between the performing and billing entities. The language in the preamble, however, contradicts the plain meaning of the rule:

Where the TC or PC is performed in the office of the billing physician or other supplier, the billing supplier will be able to recoup some or all of the overhead it incurs in the performance of the TC or PC by billing at the fee schedule amount (or at the Medicare limiting charge amount). If, however, the billing supplier has incurred overhead expenses for a TC or PC that was performed at a site other than the office of the billing supplier (such as space leased by a billing group practice and utilized by the group practice as a "centralized building" that does not meet the definition of "office of the billing physician or other supplier" at 414.50(a)(2)(iii)), the billing supplier will not be able to recoup the overhead, but rather will be limited to the lowest of the performing supplier's net charge, the billing supplier's actual charge, or the applicable fee schedule amount. (In the unlikely event that the lowest of the three amounts is either the billing supplier's actual charge or the applicable fee schedule amount, the billing supplier may be able to recoup its overhead but nevertheless would be receiving less payment than the performing supplier's net charge.) We believe that this result is appropriate. *If billing suppliers were able to recoup overhead incurred for TCs and PCs that are performed at sites other than their offices, the effectiveness of the anti-markup provisions would be undermined, because there would be an incentive to overutilize to recover the overhead incurred for purchasing or leasing space.*

72 Fed. Reg. 66319 (November 27, 2007) (emphasis added).

#### Effect on Stark "Same" and "Centralized" Building Rules

Altering the anti-markup rule so that it extends to the professional component—without regard to whether the test was purchased or not—vitiates the existing Stark regulations. This is so because, under the final version of the rule, to avoid the anti-markup provisions, a test would have to be furnished "in the office of the billing physician or other supplier," *i.e.*, the "space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally" rather than using the "same building" test specifically allowed in the Stark regulations when providing ancillary services, including diagnostic tests in a physician's office. In other words, the new rule prohibits full payment for physician arrangements that were structured to meet the Stark requirements of the in-office ancillary services exception with respect to the provisions concerning "same" and "centralized" buildings (locations which are specifically identified within the Stark statute itself). As a result, thousands of physician practices—after relying upon CMS guidance with respect to the physician self-referral laws and regulations—will not be reimbursed for equipment, facility, overhead, or any other related expenses for providing imaging or other diagnostic procedures to its

patients. Hence, it will not be possible for physician practices to offer these services without operating at a loss. As a result, when these services are no longer available, patients will lose access to quality services.

**The Statutory Basis and Regulatory History of the Anti-Markup Provision.**

The anti-markup statute upon which CMS has based its authority to promulgate this new rule is rooted in a legislative mandate precluding physicians from profiting from tests they do not perform. The final anti-markup rule issued by CMS goes far beyond the Congressional intent of the statutory provision to include the technical and professional components of tests physicians do perform. Interestingly, as drafted, the statute does not define or otherwise refer to tests having components, *i.e.*, the “technical” and the “professional” components. The statute states as follows:

[i]f a physician’s bill or request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1395x(s)(3) of this title (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test . . . . payment for the test (less applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier’s reasonable charge (or other applicable limit) for the test.

42 USC 1395u(n)(1)(A). If the claim fails to identify who performed the test, or, for a test performed by a supplier, does not include the amount charged by a supplier, then no payment may be made. 42 USC 1395u(n)(1)(B).

The anti-markup regulation, which is codified at 42 C.F.R. § 414.50 was originally promulgated by CMS in 1991, and is, for all intents and purposes, as straightforward as the statute upon which it is based. Simply put, the regulation limits payment to physicians for diagnostic tests performed by an outside supplier, but billed by the physician. As with the statute, the regulation does not refer to separate components of a diagnostic test. This distinction came later, when CMS chose to issue guidance regarding the anti-markup policy in its Medicare Carriers Manual, rather than in regulations, which are subject to notice and comment requirements under the Administrative Procedures Act.

Currently, the division of diagnostic tests into two components (for billing and payment purposes) is addressed exclusively in the CMS On-line Manual 100-04 (Medicare Claims Processing) under Chapter 1, General Billing Requirements (“Manual”). According to the Manual, a physician (or medical group) may submit a claim for the technical component of a diagnostic test which the physician or group purchases (from an independent physician, medical group, or supplier).<sup>1</sup> Significantly, this section of the Manual focuses on *two* prohibitions: (1) the physician or medical group *may not markup* the charge (for the technical component) from the purchase price; and, (2) a physician or medical group *may not “purchase”* a diagnostic test unless the physician or a member of a medical group *actually performs the interpretation* (professional component) of the test. CMS On-Line Manual 100-04, section 30.2.9.

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<sup>1</sup> This payment procedure does not include clinical diagnostic laboratory tests, which are subject to separate payment procedures.

These are two distinctly different prohibitions: one is an *anti-markup* provision; the other an *anti-billing* provision.

In the preamble to the final anti-markup rule, CMS states that it has the “authority under sections 1102(a) and 1871(a) of the Act ([its] general rulemaking authority) to impose anti-markup provisions on the TC and PC of diagnostic tests in order to fully effectuate the Congress’ intent in enacting section 1842(n)(1) of the Act.” 72 Fed. Reg. 66309 (November 27, 2007). However, the fact that CMS chose to break out the technical component and professional component in the Manual provision does not establish the requisite statutory basis for applying the anti-markup provision to both the technical and professional components of diagnostic tests. The issuance of a manual provision is not equivalent to the passage of legislation. The Manual provision was not implemented due to a legislative mandate, nor through notice and comment rulemaking—but through the less formal and less authoritative CMS issuance of a Manual provision.

Applying the new anti-markup provisions to the professional component of a diagnostic test, as well as to tests that are clearly not purchased, is not supported by the statute or its legislative history. The statute does not refer to “technical” and “professional” components of diagnostic tests, because, in using the term “test,” Congress clearly intended only to subject the *technical* component to the anti-markup rule. In other words, the statute does not address the physician service, *i.e.*, the interpretation or “professional component,” because Congress was only concerned with markups on the *technical* components of tests that are purchased by a physician who does not provide the interpretation. Allowing the professional portion of a diagnostic test, as well as tests that are personally performed by a physician or physician group, to be subjected to the anti-markup provision is unsupported by the statute.

### **The New Finalized Anti-Markup Rule Is Both Inconsistent With the Proposed Rule And Contrary to Statute**

AUA submits that CMS’s final anti-markup rule is contrary to statute and its implementation is in violation of requirements under the federal Administrative Procedure Act (“APA”). CMS itself recognizes that the statute does not establish an anti-markup provision for the professional component of diagnostic tests; however, CMS appears to be dismissing the statutory omission as “inadvertent.”

Although the Congress did not establish an anti-markup provision in section 1842(n)(1) of the Act or elsewhere for the PC of diagnostic tests, the omission may have been inadvertent. That is, it is not immediately clear why the Congress, if it wished to prevent overutilization of diagnostic testing, would not have desired an anti-markup on the PC, because without such a provision, the incentive to order unnecessary tests (and profit on the PC) remains. We believe that, in order to fully effectuate the Congress’ intent to prevent or limit the ordering of unnecessary diagnostic tests, it is necessary to impose an anti-markup provision on the PC of diagnostic tests.

72 Fed. Reg. 66315 (November 27, 2007).

Notwithstanding CMS’ claim to the contrary, it is evident in the legislative history that Congress intended to direct the anti-markup provision *only* to the technical component of purchased tests and *not*

the interpretation or personally-performed tests. The House Conference Report No. 100-495 accompanying OBRA (P.L. 100-203) addressed the anti-markup provision as follows:

The conference agreement would eliminate the physician mark-up for services obtained from outside suppliers....The mark-up is eliminated as follows: If a physician bills a global fee for a service (i.e., a fee for technical and professional components combined), the carrier limits the global fee to the sum of (i) the reasonable charge for associate professional services plus (ii) the lower of the reasonable charge for the technical component of the test or the actual acquisition cost (net of any discount). If a physician bills separately for a technical and professional component, then separate limits apply. Carriers would gap-fill any professional component fees for which they did not have established allowances.

H.R. Rep. No. 100-495, at 605-606 (1987). This language indicates that the statute is concerned with eliminating the markup on the technical component, not the professional component. Congress clearly intended to set out a different reimbursement methodology for the professional component (reasonable charge) versus the technical component (anti-markup/actual acquisition cost). The following statement from the House Report makes this obvious:

The committee provision is based on the concern that excessive payments are being made for many purchased diagnostic tests.

H.R. Rep. No. 100-39(II), at 953 (1987). CMS's new rule is not based on—and is in fact contrary to—the Congressional intent in passing the anti-markup portion of the statute because it is applying the anti-markup provisions not only to the professional component of tests, but also to tests that were provided by, rather than “purchased” by, the billing physician. In fact, the statute specifically declines to apply the anti-markup provision when the test is performed by a physician in the practice.

It is a well-established law that an agency's regulation cannot stand if it is arbitrary and capricious or manifestly contrary to the statute. *See Ragsdale v. Wolverine World Wide*, 535 U.S. 81, 91 (2002)(Supreme Court rejected a Department of Labor's rule as manifestly contrary to the statute and as an unreasonable choice because it was incompatible with the FMLA's comprehensive remedial mechanism). Further, an agency rule is considered in case law to be “arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Manufacturers Assoc. v. State Farm*, 463 U.S. 29, 43 (9th Cir. 1983); *see also National Assoc. of Home Builders, et al. v. Defenders of Wildlife et al*; *EPA v. Defenders of Wildlife*, 127 S. Ct. 2518, 2530 (2007).

Here, Congress had the opportunity to apply the anti-markup provision to the professional component and tests that were not “purchased,” but it clearly chose to limit the applicability of the statute. That CMS has chosen to expand the law to place the professional component, and services which are not purchased, within the ambit of the anti-markup limitations—in complete contradiction to the statute and Congressional intent—is a clear indication that CMS has acted beyond its jurisdiction by usurping legislative authority.

To compound the mischaracterization of the statute's scope, CMS failed to give notice to the healthcare community by finalizing a rule that was significantly different than the proposed rule. Under the APA, agencies must include in their notice of proposed rulemaking "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). In addition, they must give "interested persons an opportunity to participate in the rulemaking through submission of written data, views, or other arguments." 5 U.S.C. § 553(c). Further, "[w]hile an agency may promulgate final rules that differ from the proposed rule, a final rule is a 'logical outgrowth' of a proposed rule only if interested parties 'should have anticipated that the change was possible, and thus reasonably should have filed their comments during the notice-and-comment period.'" *Int'l Union, United Mine Workers of Amer. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

Here, the proposed rule and its preamble discussed the possibility of distinguishing full-time employees from part-time employees and independent contractors for purposes of determining whether the anti-markup provisions on the technical and professional component of diagnostic tests would apply. 72 Fed. Reg. 38122, 38225 (July 12, 2007). The final rule, on the other hand, included a wholly different test that distinguishes whether the anti-markup rule would apply based on the site of service of the test. The final rule creates new criteria which are inconsistent with the Stark rules promulgated by the same agency. The Stark rules, which are intended to address overutilization, contain an exception for in-office ancillary services. This exception, which was subject to no less than two rulemakings, determines under what circumstances ancillary services, including diagnostic tests, could be provided by physicians. Without notice by CMS, stakeholders could never have expected that the anti-markup rule would be based on a location test that is actually *contrary to* the Stark in-office ancillary services statutory and regulatory exception.

The rule as finalized is a *major* departure from what had been proposed. It has effectively deprived "interested persons" of the opportunity to address the legal, practical, and otherwise substantive flaws in the final rule. The finalizing of this rule constitutes an administrative action that is subject to challenge under the APA. See *Kooritzky v. Reich*, 17 F.3d 1509 (D.C. Cir. 1994); *Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 116 F.3d 520 (D.C. Cir. 1997); *Int'l Union, United Mine Workers of Amer. v. Mine Safety & Health Admin.*, 407 F.3d 1250 (D.C. Cir. 2005).

**CMS Is Acting Beyond Its Authority In Altering the Anti-Markup Rule Where the New Rule Effectively Vitiates Existing Stark Laws**

CMS notes in the preamble to the final anti-markup regulations that it is concerned with overutilization of tests. Such concerns are more appropriately addressed by the Stark self-referral statute and not through anti-markup rules. Nevertheless, CMS has improperly chosen to use the new anti-markup rule to address self-referral issues. If changes are necessary to meet CMS's concerns regarding self-referrals, then these changes should be made to the Stark regulations through notice-and-comment rulemaking, not through the anti-markup rule. CMS's new anti-markup rule fails to seriously address the nullification of the use of the in-office ancillary services exception for services performed in a centralized building, merely concluding that the Stark regulations and the anti-markup rule are two different regulations and while the Stark regulations prohibit billing, the anti-markup rules simply limit the amount that is allowed to be billed. However, if a physician is limited to billing a net charge that cannot include space or equipment, the practical effect of the regulation is to halt the provision of services by physicians if the anti-markup rule applies. Generally, an agency must demonstrate it has

engaged in a “reasoned decision making” process. *Fox Television Stations v. FCC*, 280 F.3d 1027, 1047 (D.C. Cir. 2002). Even if CMS manages to justify “inconsistencies” in its reasoning in this case, it most certainly did not engage in the proper procedure here. Medicare law states that “[n]o rule, requirement or other statement of policy...that establishes or changes a substantive legal standard governing the scope of benefits, payment for services...shall take effect unless it is promulgated by the Secretary by regulation...”. 42 U.S.C. § 1395hh(a)(2). The application of the anti-mark-up provision to services performed outside of the billing physician’s office and the change in the definition of “office” under 42 C.F.R. § 414.50 constitute new rules that did not go through proper rulemaking procedure. This is so because such changes re-work long-established Stark law and CMS’ own rules and guidance with respect to self-referrals.

**CMS Is Acting Beyond Its Authority in Altering the Anti-Markup Rule Where the New Rule Effectively Changes Established Payment Methodology**

By finalizing a rule that only permits physician providers to be reimbursed for a *portion* of their costs, CMS is in effect changing the methodology of payment for diagnostic tests. Rather than making payment on a fee schedule basis CMS is now creating a “net charge” system that is *intended* to reimburse providers *below cost*, with the ultimate goal of eradicating the provision of diagnostic services by physician groups under “same building” or “centralized building” arrangements. The Physician Fee Schedule makes allowances for overhead. In fact, the amount of the technical component, which is established in CMS’ fee schedule, contains an intricate calculation for practice expense (PE) that deliberately includes clinical labor, medical supplies and equipment costs for each procedure. This PE calculation is itself subject to notice and comment as part of the physician fee schedule regulations. Altering the payment methodology for diagnostic tests, without a statutory basis, without a reasoned decision-making process, and without adequate notice, constitutes an *ultra vires* act by CMS. As such, it is subject to the same legal challenges discussed above.

**CMS’ Ultra Vires Action Will Affect Existing Physician Practice Arrangements and Will Ultimately Have Serious and Detrimental Repercussions With Respect to Patient Care**

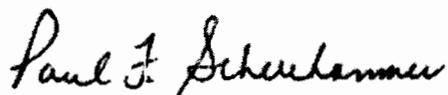
The AUA feels strongly that CMS should hold the finalization of this rule in abeyance until further discussions are held between the agency and the health care community. If the rule goes into effect as directed by CMS, the ramifications will be significant and far-reaching. Thousands of existing relationships will be effectively undone by the drastic economic impact of the new rule. As difficult as it will be for so many physician practices to dismantle (and likely never reassemble) arrangements to provide diagnostic testing services to their patients, the more important—and devastating—effect will be on patient care. Not only will high-quality diagnostic services be more difficult for patients to access, there may well be little incentive (even a disincentive) for physician practices to invest in innovative and high-quality medical technology.

The AUA reminds CMS that it should not be substituting its policy objectives at the expense of patient care. The AUA feels strongly that government policy should permit the practice of good medicine, rather than thwart advances in healthcare. When the Medicare system was instituted it was specifically designed to allow physicians to retain their autonomy over professional decision making. In fact, the statute provides that “[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which

medical services are provided.” 42 U.S.C. § 1395 (1992). The Senate Finance Committee Report also stated that physicians would retain their autonomy. “The bill specifically prohibits the Federal Government from exercising supervision or control over the practice of medicine, the manner in which medical services are provided, and the administration or operation of medical facilities....The responsibility for, and the control of, the care of the beneficiaries rests with the hospitals, extended care facilities, the beneficiaries’ physicians, etc.” S. Rep. No. 404, 89<sup>th</sup> Cong. 1<sup>st</sup> Sess. 54 (1965) reprinted in 1965 U.S. Code Cong. & Admin. News, 1943, 1965. The AUA respectfully submits that CMS reconsider its position in light of the potentially devastating impact on the quality of care for Medicare beneficiaries.

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, Sr. Manager of Quality Initiatives and Health Policy, at 410-689-3762 or [rhudson@auanet.org](mailto:rhudson@auanet.org).

Sincerely,

A handwritten signature in cursive script that reads "Paul F. Schellhammer".

Paul F. Schellhammer, M.D.  
President

**Submitter :** Ms. Ann Honeycutt  
**Organization :** Cardiology Advocacy Alliance  
**Category :** Health Care Provider/Association

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attached comment from the Cardiology Advocacy Alliance.

CMS-1385-FC-281-Attach-1.PDF

CMS-1385-FC-281-Attach-2.PDF



National leadership on issues that affect cardiovascular patients and their physicians

734.878.2108 ▪ [cardiologycaa.com](http://cardiologycaa.com)

December 31, 2007

The Honorable Kerry Weems, Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1385-FC  
P.O. Box 8020  
Baltimore, MD 21244-8020

**RE: CMS-1385-FC - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.**

Dear Administrator Weems:

The Cardiology Advocacy Alliance (CAA) represents more than 5,000 independent private practice cardiologists nationwide who provide care to our nation's Medicare population. Our mission is to provide national leadership on legislation, policies, and reimbursement methodologies that affect the quality of patient care and access to services as well as the stability of cardiovascular group practices.

CAA appreciates the opportunity to comment on the final rule referenced above and is eager to share information with CMS about the challenges that private practice independent cardiologists face in providing care to the Medicare population in a positive, open and mutually beneficial process.

## **CODING--ADDITIONAL CODES FROM 5-YEAR REVIEW**

Bundling of CPT Code 93325 into Doppler Echo Codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350 and assign CPT code 93325 a status indicator of "B" (Bundled)

CAA appreciates CMS ' decision to halt implementation of this provision and wait for the bundling 93307 with 93325 and 93320. As recommended by the specialty societies, we support a new bundled CPT code that will be valued by the RUC in September 2008. We will encourage the RUC to assess all costs involved with these procedures to ensure an appropriate level of reimbursement under the new CPT code.

## **PHYSICIAN SELF-REFERRAL PROVISIONS**

### **Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests**

CAA appreciates that CMS has delayed implementation of the revisions (with some exceptions) to the rule prohibiting the mark-up of diagnostic tests. Substantial modifications of this rule were published for the first time in the final 2008 Physician Fee Schedule (PFS) and CAA joined numerous organizations in urging CMS to delay implementation of this provision.

Although implementation of the provision has been delayed, CAA nonetheless would like to comment on the anti-markup rule in hopes that our comments will be reviewed as CMS endeavors to clarify further the provision in 2008. The provision would prohibit physician practices from "marking up" certain diagnostic tests and specifically excludes diagnostic tests that are performed personally by, or supervised by, the billing physician or another physician "with whom [the billing physician or entity] shares a practice." Accordingly, the implementing regulation, 42 C.F.R. § 414.50, currently limits application of the anti-markup rule to the technical component of diagnostic tests purchased from an outside supplier.

The Notice of Proposed Rulemaking for the CY 2008 PFS proposed tightening and clarifying the anti-markup rule as it applies to technical component services and extending it to the professional component of diagnostic tests. It did not propose extending it to diagnostic services provided within a physician group.

Under the final rule, however, CMS expanded the anti-markup rule to apply to services provided within a group practice. Specifically, CMS expanded the anti-markup rule to apply to both the professional component and the technical component of a diagnostic test provided "outside of the office" of the billing entity. Notably, when the billing entity is a "physician organization" [i.e., a "group practice" for the purposes of the federal restriction on physician self-referral], the "office of the billing physician or other supplier" is defined narrowly as "space in which the physician organization provides *substantially the full range of patient care services* that the physician organization provides generally." [Emphasis added.]

Where a diagnostic test is provided in a place other than the location (if any) where a physician group provides substantially the “full range” of its patient care services, the group will be required to include a “per procedure” charge on the Medicare claim for the test, as if the group were purchasing the test from an outside supplier rather than providing it directly. The practice will then be paid the lesser of the PFS amount or the internally generated “charge.” If no “charge” is reported on the claim, the practice will not be paid, and the group may be subject to significant sanctions.

Significantly, while there is no definite guidance on how to calculate a “per procedure” charge for services performed by an employee technician or physician, the preamble of the rule suggests that the employee’s salary should be the sole factor used in determining the charge. In other words, physicians and medical groups may not be reimbursed for equipment, facility, overhead or any other expenses for providing diagnostic procedures that they are legally entitled to provide under the federal physician-self referral regulations.

Informal discussions with CMS personnel suggest that the expanded anti-markup rule will be applied strictly, leading to nonsensical results. For example, under the rule, a cardiologist who performs a nuclear study in his practice’s office across the street due to radiation safety regulations would have to generate a charge to the i r practice. A cardiology practice that operates a diagnostic facility in an outlying office in a medically underserved area would be subject to the anti-markup rule as well.

In some situations, it is unclear whether there will be any location where the group provides the “full range” of its patient care services. For example, consider a surgical practice that provides substantial services to hospital inpatients. Does any non-hospital location provide the “full range” of the practice’s patient care services? Ironically, the larger a group practice is, the less likely that it will have any space where it provides the “full range” of its services. For example, consider a large multi-specialty clinic whose services are located throughout a medical complex. There may be no office where the “full range” of services is provided: Hence the anti-markup prohibition may apply regardless of where the diagnostic test is provided.

We believe that the application of the anti-markup rule to services provided within a bona fide group practice far exceeds CMS’s statutory authority; the statute specifically precludes application of the rule to services provided by physicians who “share a practice.” Moreover, the expansion of the rule to services provided within group practices was never subject to notice and comment rulemaking, and is implicitly inconsistent with the federal self-referral regulations, which explicitly authorize group practices to provide these services.

In addition, the rule is ambiguous on its face; clearly, providers will struggle to understand the impact of this rule. **CAA urges CMS to work with specialty organizations whose members are affected by the provision in 2008 to clarify how the provision will be implemented in 2009.**

## **Cardiac Catheterization Procedures**

CAA is concerned with the proposed 2008-2010 PE RVUs established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact on the practices and patients of our members that would result if these RVU changes are implemented. The impact of the PE RVU changes would be devastating to outpatient cardiac catheterization laboratories (OPCLs) and has the potential to force these facilities to exit the market. As a result, Medicare beneficiaries would be denied access to high quality, convenient cardiovascular services at a reasonable cost. In addition, the overall cost to the Medicare program and the coinsurance obligation for Medicare beneficiaries for these services would increase dramatically if OPCLs are forced to close.

CAA joins other organizations, including the Cardiovascular Outpatient Center Alliance (COCA), in asking CMS to either increase the PE RVUs for cardiac catheterization or allow them to be carrier priced in 2008 to provide additional time for COCA to work with Medicare in resolving this issue. CAA and its 5,000 physician members fully support COCA's efforts, data-gathering processes and positions to date on this issue and urge CMS to continue working with COCA to ensure that Medicare patients have access to outpatient cardiac catheterization services.

CAA appreciates this opportunity to comment on the final revisions to Medicare, Physician Fee Schedule and other Part B payment policies for CY 2008. Please contact CAA's executive director, Margo Burrage, at 734.878.2108 or via email at [mburrage@cardiologycaa.com](mailto:mburrage@cardiologycaa.com) if you have any questions or would like to schedule a meeting to review our comments.

Sincerely,

Ann E. Honeycutt, President  
Cardiology Advocacy Alliance

Matthew Phillips, MD  
Vice President, Medical Affairs  
Cardiology Advocacy Alliance

**Submitter :** Dr. Nina Antoniotti  
**Organization :** Marshfield Clinic  
**Category :** Health Care Provider/Association

**Date:** 12/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1385-FC-282-Attach-1.DOC

**2007 CPT Code Requests for Telemedicine  
2009 Physician Fee Schedule**

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**CPT CODE REQUESTS**

This request for additions to the list of approved Medicare TeleHealth services is submitted according to the CMS published guide in the Federal Register Vol 67, No 251, Tuesday, Dec 31, 2003, s410.78(f), and on the CMS website [www.cms.hhh.gov](http://www.cms.hhh.gov) accessed 10/21/03.

The Marshfield Clinic TeleHealth requests that Diabetes Outpatient Self-Management Training Services (DSM) G0108 and G0109, be added to the approved list of CPT codes for 2009. This request is being submitted prior to December 31, 2007, for consideration in the 2008 physician fee schedule process.

**Diabetes Outpatient Self-Management Training Services (DSM)  
(Individual Session – G0108 and Group Session – G0109)**

Marshfield Clinic TeleHealth, on behalf of its, request that CMS add Diabetes Self-Management Training G0108 and G0109 to the list of TeleHealth approved CPT codes and add Certified Diabetes Educators to the list of approved and eligible practitioners who may bill for TeleHealth services, based on the following:

- 1) Evidence exists and has been provided that diabetes self-management training improves clinical outcomes for persons with diabetes in:
  - a. Reducing HbA1c levels;
  - b. Improving blood pressure;
  - c. Reducing incidence of micro-vascular complications of diabetes;
  - d. Improves motivation to comply with treatment regimens;
  - e. Provides group peer support as an incentive to change behaviors;
- 2) Evidence exists that group education sessions provide valuable clinical and educational support to the diabetic person;
- 3) Evidence exists that certified diabetes programs and certified diabetes educators have been approved by CMS as the evidence-based practice necessary to support the diabetic person and to achieve the best possible clinical outcomes;
- 4) Evidence exists that diabetes self-management provided via TeleHealth is equal to or slightly better than providing services in-person based on the clinical outcomes of HbA1c levels;

- 5) Evidence exists that diabetes self-management provided via TeleHealth is vastly superior to no self-management training on HbA1c levels, blood pressure, compliance with treatment plans and overall quality of life for persons with diabetes;
- 6) Evidence exists that CMS has approved new codes for the list of TeleHealth approved codes without scientific proof that the new service when provided via TeleHealth does not affect the diagnosis or intervention plan (Psychiatric Interview 90801, Dialysis codes of G0308,-G0309, G0311-G0312, G0314-G0315, and G0317-G0318);
- 7) Evidence exists that CMS has approved new practitioners (Medical Nutritional Therapists and other Nutrition Professionals) without legislative mandate;

There is clearly a link between reducing complications of diabetes in persons who receive diabetes self-management training, and there is clearly support for providing services via interactive TeleHealth. With the shortage of registered nurses, and the growing shortage of diabetes educators, a clear choice emerges in terms of adding Diabetes Self Management codes G0108 and G0109 to the list of approved TeleHealth codes. MARSHFIELD CLINIC TELEHEALTH requests that Diabetes Self Management G0108 and G0109 be added to the list of approved TeleHealth codes.

In reviewing and approving requests for new CPT codes to be added to the existing list of TeleHealth codes, CMS applies two categorical assumptions to the request – is the service similar to office and other outpatients visits, consultations, and office psychiatry services, or is it not? When CMS deems that the request is similar to currently existing TeleHealth CPT codes, the request is approved. When CMS determines that the request is not similar to currently approved codes, the request is required to be supported by scientific, peer-reviewed clinical trial dMarshfield Clinic TeleHealth that supports the elements that 1) the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person (CMS uses the term face-to-face) care. The intent is to determine whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face “hands on” delivery of the same service (Fed Reg/Vol 70(151), Aug 8, 2005, p. 45786).

In the case of Diabetes Outpatient Self- Management Training (G0108, G0109), the diagnosis is not made as a part of the diabetes self-management training process. The diagnosis is made as a result of extensive primary care evaluation which is done in person, with laboratory and other diagnostic supportive evidence indicating any one of a group of metabolic disorders characterized by high blood sugar levels caused by a defect in insulin secretion, action, or both ([www.medicinenet.com](http://www.medicinenet.com), accessed 21-11-2007). The patient is managed in person or through a combination of in-person and telemedically-based care by the primary care provider in conjunction with an endocrinologist, if available. Once the patient is referred to diabetes management staff, the patient has already been diagnosed and an intervention plan is identified and documented (whether the patient will be on an anti-glycemic or insulin, how often HbA1C levels should be drawn, nutritional issues are identified and documented, and the patient’ treatment plan is

outlined and documented). The diagnosis is not changed during diabetes self-management education, as the purpose of diabetes self-management training is not to make a diagnosis or to provide therapeutic interventions. The purpose of the service is to provide education. Therefore, the criteria for analysis of Category 2 services cannot be applied to the decision taxonomy used by CMS for this request to add G0108 and G0109 to the approved list of TeleHealth CPT codes. Rather, we request that CMS use the same process applied in 2004 when Medical Nutrition Therapy and Dialysis codes were added to the TeleHealth list. At that time, CMS looked at the merits in the form of clinical outcomes of providing service and evidence-based practice (the most current strategy for determining appropriate care) in determining if the codes should be added. Additionally, CMS added Medical Nutrition Therapists and other nutrition professionals to the list of approved practitioners without legislative mandates. We request that CMS use the same process for evaluating the CPT code submission in 2007 for Diabetes Management codes G0108 and G0109.

Diabetes self-management is an interactive, collaborative, ongoing process involving the person with diabetes and the educator(s). The process includes 1) assessment of the individual's specific education needs; 2) identification of the individual's specific diabetes self-management goals; 3) education and behavioral intervention directed toward helping the individual achieve identified self-management goals; and 4) evaluation of the individual's attainment of identified self-management goals (Mensing et. al. *Diabetes Care*, 23(5), May 2006, p. 685). No part of diabetes self-management involves making a diagnosis or providing therapeutic intervention. The process goals are only assessment and education.

Diabetes self-management education is the cornerstone of care for all individuals with diabetes who want to achieve successful health related outcomes (Mensing et. al. p. 682). The American Diabetes Association has set national standards for diabetes self-management and programs using those standards must go through a rigorous process of certification in order to maintain a certified diabetes program. The standards are reviewed on an ongoing basis to reflect advances in scientific knowledge and health care.

CMS itself recognizes the importance of diabetes self-management. The Medicare website indicates, "Medicare approves certain diabetes self-management training services to help beneficiaries successfully manage their disease. A beneficiary can receive diabetes self management training services if he or she is at risk for complications from diabetes, has been recently diagnosed with diabetes, or has diabetes and is now eligible for Medicare" ([www.com.hhs.com/DiabetesSelfManagement](http://www.com.hhs.com/DiabetesSelfManagement) accessed 12-11-2007). In addition, Medicare states that "Medicare covers services to help people with diabetes manage their condition so they can prevent or reduce the severity of diabetes-related complications" ([www.com.hhs.com/DiabetesSelfManagement](http://www.com.hhs.com/DiabetesSelfManagement) accessed 12-11-2007). Section 4105 of the Balanced Budget Act of 1997 permits Medicare coverage of diabetes outpatient self-management training services when these services are furnished by a certified provider who meets certain quality standards.

The goal of medical care for people with diabetes is to optimize glycemic control and minimize complications. The Diabetes Control and Complications Trial (DCCT) demonstrated that treatment that maintains blood glucose levels near normal in type 1 diabetes delays the onset and reduces the progression of micro vascular complications (American Diabetes Association Position Statement, 2007. *Diabetes Care*, 30:S86-S87). To achieve optimal glucose control, the person with diabetes must be able to access health care providers who have expertise in the field of diabetes. Treatment plans must also include self-management training (p. S86).

The goal in management of diabetes is the achievement of near-normoglycemia, which can delay the onset or progression of diabetes-related complications, improve quality of life and reduce the economic burden associated with diabetes (Shojania et al. *JAMA*, 2006. July;296(4):427-40). Despite the fact that clinical guidelines are widely disseminated, glycemic control continues to be sub optimal (Change et al. 2007. *Dis Management Health Outcomes*, 15(6): 377-382). Factors that have contributed to the poor outcomes include insufficient physician time and adherence to recommended diabetes practice guidelines, the lack of adequate information systems, and the burden of daily management of diabetes that is placed on patients (p. 378). Diabetes care management programs have been the answer to the problem and have been implemented and supported by private and government payers as the method to improve quality of care to diabetes patients. Registered nurses are integral to the success of diabetes management programs (Knight et al. *Am J Managed Care* 2005 Apr;11(4):242-50).

Diabetes requires complicated treatment and self-discipline on the part of the patient. Education is essential to its management (Siminerio, *Diabetes Spectrum* 19:76-78, 2006). Diabetes complications are some of the most serious of all chronic conditions and many are the result of behaviors of the patient. The education process and certification for diabetes education was started in the early 1970s by Dr Donnell Etzweiler. Traditionally, clinical outcomes had been measured in terms of changes in HbA1C levels and knowledge base. Behavior change is also now an appropriate outcome for measuring the effectiveness of diabetes education. Over 90 percent of patients with diabetes receive their care from primary care providers (Janes, GR, *Diabetes in America*, 2<sup>nd</sup> Ed., 1995, p. 541-552, NIH publ. 95-1468). Therefore, effective implementation of diabetes education programs in primary care settings requires innovative ways of spreading the resources of certified diabetes educators in the vast primary care setting. The use of TeleHealth is an appropriate tool to do so. CMS has already approved MEDICAL NUTRITION THERAPIST for TeleHealth, which is an education based service which does not make a diagnosis or provide therapeutic interventions, and thus sets a comparative value (similar service in the existing list of approved TeleHealth codes) for Diabetes Self Management. Medical Nutrition Therapy and Diabetes Self Management provide exactly the same service; both are designed to provide education in the primary care setting and to facilitate behavior modification on the part of the patient.

We believe that the actual analysis of whether or not Diabetes Self Management codes G0108 and G0109 should be added to the current list of TeleHealth CPT codes must be based on the analysis of the evidence that providing diabetes self-management training by

registered nurses has a direct effect on reducing HbA1c levels and improves outcomes for patients (limits the development of micro vascular complications of diabetes) and not on the comparison of providing services in-person versus over TeleHealth. In Marshfield Clinic's programs, patients who receive their care via TeleHealth have similar if not the same HbA1c level. The diabetic patient is care for under the protocols developed by the PGP project, in which Marshfield Clinic is one of ten sites. Recently, Marshfield Clinic was noted as having saved CMS the most money in terms of reduced costs in the first year of the project. One of the tools used in the project is TeleHealth and access to the right specialists at the right time through TeleHealth (including diabetes educators).

Specific to telemedicine, Izquierdo and his colleagues (2003) conducted a study to determine whether diabetes education can be provided as effectively through telemedicine technology as through in-person encounters with diabetes nurse and nutrition educators (*Diabetes Care*, Vol 26(4), April, P. 10021007). A total of 56 patients with diabetes were randomized to receive diabetes education via telemedicine or in person (control group). The groups were compared using measures of HbA1c and questionnaires to assess patient satisfaction and psychosocial functioning as related to diabetes. Outcome measures were obtained at baseline, immediately after completion of the education program, and at three months after the third educational visit. Results indicated that patient satisfaction was high in the telemedicine group, Problem Areas in Diabetes scale scores improved significantly with diabetes education immediately after education and three month after education, and the attainment of behavior-change goals did not differ between groups. With diabetes education HbA1c improved from 8.6 (+/- 1.8%) at baseline to 7.8(+/-1.5%) immediately after education and 7.8 (+/- 1.8%) three months after the third educational visit, with similar changes observed in the telemedicine and in-person group. The conclusion of the study supported diabetes education via telemedicine and in-person care as equally effective in improving glycemic control, and both methods were well accepted by patients. Reduced diabetes-related stress was observed in both groups (p. 1002).

Dimmick et. al. (2003) conducted a study of patients receiving care over a telemedicine network that linked three hospitals and an FQHC with six sites, a dental clinic, and patient homes. Outcomes from the disease management programs conducted over telemedicine for the diabetes group showed that the diabetes disease management program increased the number of diabetics who brought their blood sugar under control (Dimmick et. al. *Telemed Journ and e-health*, 9(1): 13-23).

One component of diabetes self-management training is group visits. Group visits are a practical method of delivering extensive group education as well as some medical care (Jaber R. 2007. *DOC News*, Vol 4(2): p. 3). Diabetes is one of the top ten chronic conditions that has been effectively treated with group visits (Scott et. al. 2004. *J Am Geriatric Soc*, 52: 1463-1470). Trento (2002, *Diabetology*, 45: 1231-1239) indicates that diabetes HbA1c and retinopathy improves in patients who have been seen in group visits compared with a group receiving usual care. The Kaiser Permanente (Group Health Cooperative) have used group visits very successfully for years in the HMO setting as well as the non-HMO setting, such as private practices. Jaber R, Braksmajer A,

Trilling J. 2006. *Fam Pract Manag*13: 37-40). Group visits are an ideal format to provide patients with comprehensive care. Group visits allow the necessary time to deliver quality care with personalized education that empowers patients to acquire disease specific and general wellness skills in a supportive and supervised environment. IN addition, the group visit format provides modeling reinforcement by other patients as well s the power of the group dynamic in supporting patient goals to improve self-care (Jabar 2007, p. 4).

What is imperative is that we as health care providers and government payers come up with innovative ways to help diabetics complete education programs that are proven to positively impact clinical outcomes. Telemedicine makes it easy for diabetics to receive the education needed and for diabetes management staff to partner with primary care providers, exponentially improving outcomes even more.

Submitted December 31, 2007.

**Submitter :** Dr. Arash Kimyai-Asadi  
**Organization :** Dr. Arash Kimyai-Asadi  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

**Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007**

As a full-time Mohs surgeon in Houston, Texas, I am highly concerned that application of the Multiple Procedure Reduction Rule to the Mohs surgery codes will have a devastating effect on my patients. As many as 30-35% of my patients come to me with multiple tumors, and many of these patients travel hours to have access to Mohs surgery. I routinely perform the Mohs procedure and reconstruction on numerous tumors at one time to accommodate patients. If Mohs surgery for additional tumors are reimbursed at half the allowable rate, it will simply not be economically viable for me to provide multiple Mohs and reconstruction procedures in one session. Patients will have to make numerous trips for each tumor, and many of them will have to have their reconstruction performed by another specialist, who is likely to utilize operative room and anesthesia services, converting the \$300 purported cost savings to Medicare into a several thousand dollar bill for operating room, anesthesia and surgical services. As such, this rule change will have an awful impact on efficient access to care for patients and on the cost of treating skin cancer for Medicare. It is absolutely clear to anyone familiar with Mohs surgery that additional Mohs procedures have minimal overlap, particularly because a large portion of the work comprises pathology-related services, which are routinely exempt from the Multiple Procedure Reduction Rule. This change in exemption also creates absurdities, such as Stage 1 of Mohs surgery paying less than Stage 2 for patients undergoing flaps or grafts for reconstruction or who undergo multiple Mohs procedures. I also operate on patients in the hospital setting when necessary, and the reimbursement for Stage 1 of Mohs surgery paid at half is less than that of a shave biopsy and an accompanying frozen section. How such a drastic cut can be envisioned is difficult for me to comprehend. I implore you to, for the sake of patients, do your utmost to avoid this change in exemption for Mohs procedures.

**Submitter :** Dr. Ming Jih  
**Organization :** DermSurgery Associates  
**Category :** Physician

**Date:** 12/31/2007

**Issue Areas/Comments**

**Refinement of RVUs for CY 2008  
and Response to Public Comments  
on Interim RVUs for 2007**

**Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007**

As a board-certified general dermatologist in Houston, Texas, I am very concerned about the application of the Multiple Procedure Reduction Rule to Mohs Surgery. I refer my most complicated and difficult tumors for Mohs surgery and many of the patients I refer require reconstruction of their surgical defects, and these reconstructive procedures are typically performed by the Mohs surgeon on the same day as surgery. I also refer many patients with multiple skin cancers for Mohs surgery on a single day. This is particularly true for my elderly patients, for whom multiple trips to a Mohs surgeon is very inconvenient. The Mohs surgeons I refer to are not going to be able to perform multiple Mohs procedures on one day, and may not be able to perform reconstructive procedures on the patients either. It is critical that the exemption of Mohs surgery from the Multiple Procedure Reduction Rule be reinstated for the sake of my patients.